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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Notice of the mandatory guidelines proposed by the Secretary of Health and Human Services.

SUMMARY: The Department of Health and Human Services (“HHS” or “Department”) is proposing to establish scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines).

DATES: Submit comments on or before **[INSERT 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: In commenting, please refer to file code SAMHSA-2015-2. Because of staff and resource limitations, SAMHSA cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow “Submit a comment” instructions.

- By regular mail.* You may mail written comments to the following address ONLY: SAMHSA, Attention Division of Workplace Programs (DWP), 1 Choke Cherry RD., Room 7-1045, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

- By express or overnight mail.* You may send written comments to the following address ONLY: SAMHSA, Attention DWP, 1 Choke Cherry RD., Room 7-1045, Rockville, MD 20850.

- By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period: SAMHSA, Attention DWP, 1 Choke Cherry RD., Room 7-1045, Rockville, MD 20850. If you intend to deliver your comments to the Rockville address, call telephone number (240) 276-2600 in advance to schedule your arrival with one of our staff members. Because access to the interior of the SAMHSA building is not readily available to persons without federal government identification,

commenters are encouraged to schedule their delivery or to leave comments with the security guard front desk located in the main lobby of the building. Comments erroneously mailed to the address indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Charles LoDico, M.S., DABFT, Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), SAMHSA mail to: 1 Choke Cherry Road, Room 7-1045, Rockville, MD 20857, telephone (240) 276-2600, fax (240) 276-2610, or e-mail at charles.lodico@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:

Executive Summary

This notice of proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) will allow federal executive branch agencies to collect and test an oral fluid specimen as part of their drug testing programs. In addition, some agencies, such as the Department of Transportation, are required to follow these guidelines in developing drug testing programs for their regulated industries, whereas others, such as the Nuclear Regulatory Commission (NRC), use the guidelines as part of the regulatory basis for their federal drug testing programs. These proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and methods, confirmatory oral fluid drug test analytes and methods, processes for review by a Medical Review Officer (MRO), and requirements for federal agency actions.

These Guidelines provide flexibility for federal agency workplace drug testing programs to address testing needs and remove the requirement to collect only a urine specimen, which has existed since the Guidelines were first published in 1988. Federal agencies, MROs, and regulated industries using these Guidelines will continue to adhere to all other federal standards established for workplace drug testing programs. These proposed OFMG provide the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (URMG).

The Department of Health and Human Services, by authority of Section 503 of Public Law 100-71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. These proposed OFMG establish standards for certification of laboratories engaged in oral fluid drug testing for federal agencies and the use of oral fluid testing in federal drug-free workplace programs.

Summary of the Major Provisions of the Proposed OFMG

The promulgation of the OFMG allows federal agencies to collect and test oral fluid specimens in their workplace drug testing programs. The collection process for oral fluids provides that the specimen collection will be under observation. The OFMG enable split specimen testing by requiring two specimens to be obtained from the donor, either concurrently or serially, using separate collection devices or a single collection device that can be split into two separate specimens. Unlike the urine Mandatory Guidelines for Federal Workplace Drug Testing Programs (UrMG), Instrumented Initial Test Facilities are not practical and will not be

allowed due primarily to the limited sample volume of oral fluid collected from the donor. With the exception of 6-acetylmorphine, a metabolite of heroin, and benzoylecgonine, a metabolite of cocaine, the analytes detected in oral fluids are primarily parent compounds. The OFMG analyte cutoffs are much lower than those specified for urine in the UrMG because drug analyte concentrations in oral fluid are much lower than urine concentrations. The Department is proposing that all specimens be tested for either albumin or Immunoglobulin G (IgG) to determine whether the specimen is valid. In the event that an individual is unable to provide an oral fluid specimen, the federal agency may authorize the collection of a urine specimen. With the inclusion of oral fluid testing in federal agency workplace programs, medical review of drug test results will become more complex. The MRO must interpret laboratory reported drug test results for both urine and oral fluid specimens. To ensure that MROs remain up-to-date on drug testing issues, pharmacological and toxicological information, and federal agency rules and regulations, the OFMG require MRO requalification training and reexamination on a regular basis (i.e., every five years).

Costs and Benefits

Using data obtained from the Federal Workplace Drug Testing Programs and HHS certified laboratories, the Department estimates the number of specimens tested annually for federal agencies to be 150,000. HHS projects that approximately 7% (or 10,500) of the 150,000 specimens tested per year will be oral fluid specimens and 93% (or 139,500) will be urine specimens. The approximate annual numbers of regulated specimens for the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) are 6 million and 200,000, respectively. Should DOT and NRC allow oral fluid testing in regulated industries' workplace programs, the estimated annual numbers of specimens for DOT would be 180,000 oral fluid and

5,820,000 urine, and numbers of specimens for NRC would be 14,000 oral fluid and 186,000 urine.

In Section 3.4, the Department is proposing criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specifying the cross-reactivity of the immunoassay to the other analytes(s) within the group. These proposed Guidelines allow the use of methods other than immunoassay for initial testing. In addition, these proposed Guidelines include an alternative for laboratories to continue to use existing FDA-cleared immunoassays which do not have the specified cross-reactivity, by establishing a decision point with the lowest-reacting analyte. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

Costs associated with the addition of oral fluid testing and testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal based on information from some HHS certified laboratories currently testing non-regulated oral fluid specimens. Likewise, there will be minimal costs associated with changing initial testing to include methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) since current immunoassays can be adapted to test for these analytes. Prior to being allowed to test regulated oral fluid specimens, laboratories must be certified by the Department through the National Laboratory Certification Program (NLCP). Laboratories choosing to apply for HHS certification will incur some administrative costs associated with adding the matrix and these analytes. However, laboratories performing urine and oral fluid drug testing have trained personnel, drug testing methods, and the infrastructure (e.g., secured facilities, computer systems, and electronic reporting methods) in place. Estimated laboratory costs to complete and submit the application are \$2,000, and estimated costs for the Department to process the

application are \$7,200. The initial certification process includes the requirement to demonstrate that their performance meets Guidelines requirements by testing three (3) groups of PT samples. The Department will provide the three groups of PT samples through the NLCP at no cost. Based on costs charged for urine specimen testing, laboratory costs to conduct the PT testing would range from \$900 to \$1,800 for each applicant laboratory.

The following estimated costs are based on current costs for urine testing. Once oral fluid testing has been implemented, the cost per specimen for each initial test will range from \$.06 to \$0.20, due to reagent costs. Estimated costs for each confirmatory test range from \$5.00 to \$10.00 for each specimen reported as positive, due to costs of sample preparation and analysis. Based on information from non-regulated workplace drug testing, approximately 1% of the submitted specimens is expected to be confirmed as positive for one or more of the following analytes: oxycodone, oxymorphone, hydrocodone, and/or hydromorphone. Therefore, the added cost for confirmatory testing will be \$0.05 to \$0.10 per submitted specimen. This would indicate that the total cost per specimen submitted for testing will increase by \$0.11-\$0.30. These costs for the laboratories or federal agencies choosing to use oral fluid in their drug testing programs will be incorporated into the overall testing cost for the federal agency submitting the specimen to the laboratory. Agencies choosing to use oral fluid in their drug testing programs may also incur some costs for training of federal employees such as drug program coordinators.

Based on current figures, approximately 7% (or 10,500) of the 150,000 specimens tested per year for HHS will be oral fluid, 180,000 oral fluid specimens for DOT, and 14,000 oral fluid specimens for NRC.

The federal agencies choosing to use oral fluid in their drug testing program may see many benefits including a reduction in time of the collection process; an observed collection

method leading to reductions in rejected, invalid, substituted, and adulterated specimens; and an effective tool in post-accident testing identifying the parent or active drug. Productivity for federal agencies related to the drug free workplace program is expected to improve. For example, administrative data indicates it takes, on average, about 4 hours from the start of the notification of the drug test to the actual time a donor reports back to the worksite. Since oral fluid collection does not have the same privacy concerns as urine collection, onsite collections are likely, thereby reducing the time a donor is away from the worksite. The Department estimates the time savings to be between 1 and 3 hours. The Department believes the cost reduction as outlined in this Preamble will benefit the federal agencies and drug free workplace program.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public. Please note that all comments are posted in their entirety including personal or confidential business information that is included in a comment.

SAMHSA will post all comments before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. Comments received before the close of the comment period will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the Substance Abuse and Mental Health Services Administration, Division of Workplace Programs, 1 Choke Cherry RD., Rockville, MD, 20850, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, call (240) 276-2600.

Background

The Department of Health and Human Services (HHS) by the authority of Section 503 of Public Law 100-71, 5 U.S.C. Section 7301, and Executive Order No. 12564 has established the scientific and technical guidelines for federal workplace drug testing programs and established standards for certification of laboratories engaged in urine drug testing for federal agencies. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** [FR] on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008; [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

History and Proposed Changes to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs

A focus of the HHS mission is to maintain the integrity and ensure the quality of federal drug-free workplace programs by a commitment to identify and mandate the use of the most accurate, reliable drug tests and methods available. To accomplish that goal, the Department has implemented an ongoing scientific review and program collaboration with federal regulators, researchers, the drug testing industry, and public and private sector employers. As the use of alternative specimens (other than urine), analytical test technologies, and types of commercial workplace drug testing products have increased over the past decade in the private sector, the Department, through SAMHSA's Drug Testing Advisory Board (DTAB), has responded by

review of these new products and began a dedicated assessment of drug testing using alternative specimens, such as oral fluid (saliva), hair and sweat for possible application in federal agency workplace testing programs.

The following OFMG are the result of a directed Departmental assessment that began in 1997 with a 3-day scientific meeting of the DTAB. During that meeting, the DTAB members discussed drug testing using alternative specimens and the use of new and developing drug testing technologies that could be applicable to workplace drug testing programs. The DTAB meeting was open to the public. Following the initial meeting, members of the DTAB continued to review and analyze all available information on alternative specimens and testing technologies. These efforts resulted in identifying specific scientific, administrative, and procedural requirements necessary for a comprehensive federal workplace drug testing program that included alternative specimens and technologies.

For more than 15 years, the DTAB has continued to evaluate the science and information submitted by industry representatives on alternative specimens and technologies. The following section presents a chronology of meetings and events leading to these proposed Guidelines for the testing of oral fluid.

The first working draft of new guidelines, including the testing of alternative specimens, was presented at the June 2000 DTAB meeting. These initial, “work-in-progress” guidelines were placed on the SAMHSA website and the public was invited to submit supplemental information and informal comments to improve the draft and further SAMHSA’s knowledge base. Twenty-eight separate comments were submitted. All comments were summarized, incorporated into the draft Guidelines and presented at the next DTAB meeting held in September 2000. At that DTAB meeting, a second working (revised) draft of the Guidelines was

presented and, again, comments were requested from all interested parties. At the December 2000 DTAB meeting, the public comments submitted were used to prepare the third working draft of the Guidelines. Concurrently, SAMHSA organized three expert groups [Oral Fluid, Hair, and Sweat] that included members from science and industry.

To assess laboratory performance and utility of alternative specimen testing for use in federal workplace programs, the Department initiated a voluntary pilot proficiency testing (PT) program. This pilot program provides PT samples, developed and prepared at government expense, to a number of laboratories for testing. Participating laboratories used their routine procedures to test oral fluid, hair and sweat specimens and shared their PT results with SAMHSA. This pilot PT program was established for two reasons. The first was to determine if it was possible to prepare stable and accurate PT samples for the proposed specimen type that could be used in a laboratory certification program. Second, the PT results reported by the laboratories could be used to help establish criteria for the analysis of alternative specimens.

Based on data obtained from the pilot PT program, it appeared that valid PT samples could be prepared but refinement was needed. The results in the pilot PT program were encouraging, and both individual laboratory and collective performance improved over time; however, there remained some concern about the performance differences among the participating laboratories, and the applicability of some testing technologies used by the laboratories. By 2004, the working groups reached consensus and proposed standards for laboratory-based oral fluid, hair, and sweat testing procedures.

In April 2004, the Department issued a Federal Register notice [69 FR 19673] on the proposed inclusion of oral fluid, hair, and sweat specimens in federal workplace drug testing programs. Public comments and issues raised by federal agencies during the internal review of

the proposed changes identified significant scientific, legal, and public policy concerns about the use of the alternative specimens. As a result of the internal review, the Department issued a Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs in November of 2008 [73 FR 71858] that concluded the scientific, technical, and legal information for the testing of alternative specimens (oral fluid, hair, and sweat) was insufficient to include these specimens in the federal programs at that time. However, the Department committed to monitoring developments in alternative specimen testing and has continued to do so since 2008.

The complexity of responses to the 2004 notice made it clear that if the Department were to subsequently authorize alternative specimens for the Mandatory Guidelines for Federal Workplace Drug Testing Programs, each specimen matrix would need a separate set of guidelines. Additionally, the Department proposed to stagger the timeline for the review and potential incorporation of alternative specimens, and to begin with oral fluid. The decision to begin with oral fluid was supported by fewer legal and policy concerns, and current peer-reviewed literature that existed with oral fluid.

Methods developed since 2004 offer enhanced analytical sensitivity and specificity for testing drugs in oral fluid. The scientific literature base for oral fluid testing and interpretation of results has grown substantially. Many non-regulated private sector organizations have incorporated oral fluid testing into their workplace programs. Also, during this period, SAMHSA funded a review of a Medical Review Officer (MRO) database of laboratory-reported results for urine and alternative specimens from both regulated and non-regulated workplaces. The study showed a dramatic increase in the use of oral fluid testing from 2003 to 2009.

At the open session of the January 2011 DTAB meeting, SAMHSA shared with DTAB and the public the most current information on the oral fluid specimen. During the meeting, experts made scientific presentations concerning oral fluid as a specimen for workplace drug testing, including: physiological composition of oral fluid, tested drugs and cutoffs, collection devices, and best practices laboratory methodologies (initial and confirmatory testing).

At approximately the same time, SAMHSA entered into an Interagency Agreement (IAA) with the Office of National Drug Control Policy (ONDCP) and received funding to update and expand the laboratory standards for federal forensic drug testing. The overall goal of this IAA was to determine the state of the science for oral fluid collection, testing, and interpretation, to support the development of these proposed Guidelines to include the use of the oral fluid specimen. Additionally, the IAA required researching additional drugs of abuse that warranted addition to the existing urine specimen analyte panel. This included investigation of prescription drugs with high abuse and impairment potential.

Subsequent to the IAA and the January 2011 DTAB meeting, several working group meetings were held to discuss the oral fluid science and develop proposed Guidelines using oral fluid specimens. Working group members included federal partners, subject matter experts, industry leaders, stakeholders, and representatives from the National Laboratory Certification Program (NLCP).

In June 2011, SAMHSA solicited comments regarding the science and practice of oral fluid testing via a Request for Information (RFI) [76 FR 34086]. The notice requested written opinions from the public and industry stakeholders regarding a variety of issues related to oral fluid testing, including potential analytes, cutoff concentrations, specimen validity, specimen collection, collection devices, testing methods and interpretation of analytical results. The RFI

was an effort to give the public and industry stakeholders an additional opportunity to provide information and comments for consideration during the development of the draft Guidelines for oral fluid testing. The Department received 18 comments from drug testing laboratories, MROs, oral fluid collection device manufacturers, drug testing industry associations, and the public [available at www.regulation.gov (docket SAMHSA-2011-0001)]. All submitted comments were reviewed and were presented to the DTAB members for consideration during SAMHSA's continuing assessment of oral fluid as an alternative specimen.

At the July 2011 meeting of the DTAB, Board members voted unanimously for the following: 1) *Based on review of the science, DTAB recommends that SAMHSA include oral fluid as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs*; and 2) *DTAB recommends the inclusion of additional Schedule II prescription medications (e.g., oxycodone, oxymorphone, hydrocodone and hydromorphone) in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.*"

At the January 2012 DTAB meeting, the SAMHSA Administrator received the DTAB recommendations from the July 2011 meeting.

The DTAB recommendations, the results from the SAMHSA-funded PT program, and the private sector experience have led the Department to conclude that oral fluid should be included in the federal program as an alternative specimen.

Rationale for the Inclusion of Oral Fluid in the Mandatory Guidelines for Federal Workplace Drug Testing Programs

The scientific basis for use of oral fluid as an alternative specimen for drug testing has been broadly established.¹⁻¹² Corresponding developments have proceeded in analytical

technologies that provide the needed sensitivity and accuracy for testing oral fluid specimens.¹³⁻

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Oral fluid and urine test results have been shown to be substantially similar, and oral fluid may have some inherent advantages as a drug test specimen. Oral fluid collection will occur under observation, which should substantially lessen the risk of specimen substitution and adulteration and, unlike direct observed urine collections, the collector need not be the same gender as the donor.

What is Oral Fluid?

Oral fluid is the physiological fluid that can be collected from the oral cavity of the mouth. Oral fluid is comprised primarily of saliva produced by the submandibular, sublingual, and parotid glands.²⁹ Other sources that contribute to the composition of oral fluid are minor salivary glands, gingival crevicular fluid (fluid from between the gums and teeth), cellular debris, bacteria, and food residues.³⁰ The major constituent of oral fluid is water. Other components include electrolytes such as potassium, sodium, chloride, bicarbonates and phosphates, and organic substances such as enzymes, immunoglobulins, and mucins.³¹ The composition of oral fluid is dynamic and varies with the rate of saliva production (flow rate). The pH of saliva is generally acidic, but may range from 6.0 to 7.8, depending upon the rate of saliva flow. As saliva flow increases, levels of bicarbonate increase, thus increasing pH.³² The volume of saliva produced by individuals varies considerably from approximately 500 to 1500 mL per day. The total volume of oral fluid in the mouth after swallowing averages about 0.9 mL for adult males and 0.8 mL for adult females.³³

What is the mechanism of drug disposition in Oral Fluid?

Drugs enter oral fluid primarily by diffusion from blood and from active drug use by oral, transmucosal, smoked, inhaled, and insufflated routes. Oral cavity tissues have a rich blood supply. The movement of drugs from blood (plasma) to oral fluid depends upon certain physicochemical properties of the drug. The primary restricting factors are drug lipophilicity, degree of ionization, and the degree of drug binding with plasma proteins.³⁴ Lipid-soluble molecules pass through cell membranes more efficiently than those that are more water soluble (e.g., drug metabolites). Consequently, parent (unmetabolized) drug is frequently the predominant analyte identified in oral fluid. Biological membranes are not permeable to the drug fraction that is bound to plasma proteins or to drug that is in the ionized state; hence only free, non-protein bound and non-ionized drug in plasma can diffuse into saliva. Consequently, oral fluid drug concentrations are closely related to the free, unbound drug in blood (plasma). For those drugs that are weak bases (e.g., cocaine, opioids, amphetamines, and phencyclidine), concentrations in oral fluid frequently are higher than plasma concentrations as a result of “ion-trapping” due to oral fluid’s higher acidity relative to plasma. Despite these restrictions, drug transfer from blood to oral fluid is a rapid process as demonstrated by consistent positive tests for drug in oral fluid two to five minutes following an intravenous injection of heroin³⁵ or cocaine.³⁶ The correlations of drug concentrations in oral fluid to those in plasma vary substantially from drug to drug.⁴

Deposition of drugs in oral fluid can also occur from external sources. For example, drugs in food sources (e.g., morphine in poppy seeds) are a potential source of contamination.³⁷ Drug residues can initially be deposited in high concentration in oral fluid during active drug administration by oral, transmucosal, smoked, inhaled, and insufflated routes.^{1, 35, 36} Generally,

deposited drug residues disappear fairly rapidly because of inherent self-cleansing mechanisms of the oral cavity (e.g., saliva production and subsequent swallowing).

Detection times are influenced by many pharmacological and chemical factors associated with the drug, dose, route of administration, frequency of drug use, biology of the individual, specimen type, and the sensitivity of the detection system. In general, detection times in oral fluid are somewhat shorter than observed for urine. In oral fluid, drugs of abuse are detected for 5 to 48 hours after use, whereas in urine, the detection time is 1.5 to 4 days or longer with chronic drug use.^{11, 38} However, as described below, positivity rates for oral fluid reported for non-regulated workplace testing are the same as or higher than urine positivity rates. These rates demonstrate the equivalency of these specimen types in identifying drug use, despite differences in drug detection times.

How do testing positivity rates compare between Oral Fluid and Urine?

In the absence of paired specimen collections (i.e., urine and oral fluid from the same donor) in workplaces, the positivity rates of urine and oral fluid tests can be used to infer the relative effectiveness of these two specimen types.

The workplace positivity rates for drugs in oral fluid appear to be generally comparable to corresponding rates reported for urine. The 2013 Drug Testing Index (DTI) by Quest Diagnostics for drugs in the general workforce indicated positivity rates for oral fluid as 0.59 percent amphetamines (combined percentages of amphetamine and methamphetamine), 0.31 percent cocaine, 4.0 percent marijuana, 0.88 percent opiates, and 0.02 percent PCP and, for urine, as 0.87 percent amphetamines, 0.21 percent cocaine, 2.0 percent marijuana, 0.44 percent opiates and 0.01 percent PCP.³⁹ The overall drug positivity rate for oral fluid was 5.5 percent

compared to 4.1 percent for urine. An earlier study of 77,218 oral fluid specimens reported similar trends in the positive prevalence rates compared to the DTI for urine specimens collected during the same period.⁴⁰ In that study, the overall combined positivity rate for oral fluid was 5.06 percent compared to 4.46 percent for urine. Both sets of data compared positivity rates in two separate workplace populations over a comparable time period. The higher positivity rates for oral fluid are most likely due to the fact that oral fluid collections are performed under observation, reducing the ability of donors to substitute or adulterate the specimen.

Only limited studies have compared positivity rates from “paired” specimen collections in the same population. A clinical study involving compliance monitoring of pain patients compared test results for oral fluid to urine specimens collected in “near simultaneous fashion.”⁴¹ The specimens were analyzed for 42 drugs and/or metabolites by mass spectrometric procedures. The authors evaluated two subsets of data related to federal workplace drug testing: 263 comparisons of currently tested drugs (i.e., morphine, codeine, cannabinoids, cocaine, amphetamine, and methamphetamine) and 491 comparisons that included these drugs plus hydrocodone and oxycodone. For the first data set, 92.4 percent of the oral fluid and urine specimens had the same results (i.e., positive/positive or negative/negative). For the second data set (which included hydrocodone and oxycodone test results), 89.2 percent of the specimens had the same results (i.e., positive/positive or negative/negative). Statistically, both data sets exhibited substantial agreement in results between oral fluid and urine. The overall result discordance for the current drugs was 5.5%, of which 2.5% were positive in oral fluid and negative in urine, and 3% were negative in oral fluid and positive in urine. For hydrocodone, 9 (7.9%) analyte results were positive in oral fluid and negative in urine, while only 1 (0.09%) analyte result was negative in oral fluid and positive in urine. For oxycodone, 9 (7.9%) analyte

results were positive in oral fluid and negative in urine, and 14 (12.3%) analyte results were negative in oral fluid and positive in urine. Differences in time courses of drugs and metabolites in these matrices may explain the discordant results.

Another study compared positivity rates from paired specimens from 45 subjects (164 paired sets of specimens) of treatment patients stabilized on either methadone or buprenorphine.⁴² Aside from methadone or buprenorphine, 595 (21.1 percent) drug analytes were positive and 1948 (69.0 percent) were negative for both specimens for an overall agreement of 90 percent. There were 82 (2.9 percent) analyte results that were positive in oral fluid and negative in urine, and 199 (7.0 percent) that were negative in oral fluid and positive in urine, for an overall disagreement of 10 percent. Morphine was found more often in urine (n=66) than in oral fluid (n=48), whereas 6-acetylmorphine was found more often in oral fluid (n=48) than in urine (n=20). Amphetamine and methamphetamine were found slightly more often in oral fluid than in urine. Benzodiazepines and cannabis were found more frequently in urine.

Several studies have been reported comparing oral fluid testing to urinalysis for individuals under criminal justice supervision.⁴³⁻⁴⁵ In one study, the agreement rates between an oral fluid initial test result and confirmed urine test for 223 probationers ranged from 90 to 99 percent.⁴⁴ The lowest agreement rate (90 percent) was for marijuana, with 20 of the 23 discordant specimens negative by oral fluid and positive by urine testing. Two studies reported almost identical rates of recent cocaine and opiate use from either type of test, but oral fluid was less effective in detection of marijuana users than urinalysis.^{43,45}

How were analytes and cutoffs selected?

The selection of analytes for testing was based on known drug disposition patterns in oral fluid. Some drug disposition patterns in oral fluid are similar to urine and others differ in relative

amounts of parent drug versus metabolite and in type of metabolite. The mechanisms of drug excretion in oral fluid are somewhat different than in urine. In some cases, direct deposition of parent drug in oral fluid may occur by oral, snorted (insufflated), transmucosal, inhaled, and smoked routes of administration. When this occurs, the metabolites generally appear later in oral fluid. For some drugs (e.g., cocaine and heroin), it appears that direct hydrolysis may also occur.^{35,36} The primary means of entry into oral fluid for most drugs (and metabolites) is by passive diffusion of un-ionized, non-protein bound fraction of drug from plasma. Diffusion into oral fluid occurs more readily for lipophilic drugs than for water-soluble metabolites. As a result of these mechanisms, parent (unmetabolized) drug is frequently the primary analyte present in oral fluid. Urinary excretion occurs more readily for water-soluble metabolites; lipid-soluble drugs are frequently re-absorbed back into blood during urinary excretion.

The route of administration influences the time course of both drug and metabolites in oral fluid.⁴⁶ Orally administered drugs generally undergo some degree of metabolism in the gastrointestinal tract and liver prior to entering the bloodstream, whereas injected and smoked drugs are absorbed primarily intact without metabolite formation. Once drugs (and metabolites) enter the bloodstream, they rapidly diffuse into oral fluid by excretion from highly blood-perfused salivary glands. Consequently, oral fluid tests generally are positive for parent drug as soon as the drug is absorbed into the body. Additional information on analyte selection for each drug is provided below in Subpart C, Oral Fluid Specimen Tests. In contrast, urine tests that are based solely on detection of a metabolite are dependent upon the rate and extent of metabolite formation.

Will there be specimen validity tests for Oral Fluid?

In regard to specimen validity testing for oral fluid, the Department considered measuring various oral fluid components (e.g., amylase, albumin, and immunoglobulins such as IgG). Given that collection of oral fluid specimens will occur under observation, the Department did not find sufficient justification for extensive validity testing to identify attempts to adulterate or substitute specimens. However, both IgG and albumin in oral fluid are currently being used in the industry to identify specimen collections in which insufficient oral fluid was collected. The Department is proposing that all oral fluid specimens be tested for one of these components, but specifically requests public comment on requiring these tests.

Review of the literature for concentrations of albumin in oral fluid found that healthy subjects were characterized by concentrations ranging from 2.6-23.8 mg/dL⁴⁷ and in patients with cancer and renal failure,^{48,49} the albumin concentrations ranged from 1.0-12.2 mg/dL. These data support using the industry cutoff of 0.6 mg/dL as a decision point for albumin in oral fluid.

Literature concerning the concentrations of IgG in oral fluid found that only pre dentate babies exhibited IgG concentrations below 1 mg/L.⁵⁰ Adults with and without teeth had a concentration mean of 19 mg/L. The mean for elderly adults with teeth was 24 mg/L and the mean for edentate elderly adults was 5.2 mg/L. Young healthy adults under various exercise routines had IgG concentrations means ranging from 5 mg/L to greater than 40 mg/L.⁵¹ These data support using the industry cutoff of 0.5 mg/L as a decision point for IgG in oral fluid.

To avoid prohibiting other oral fluid specimen validity tests that may become available, the Department is also authorizing additional specimen validity testing as described in Section 3.1.d and Section 3.5.

The Department maintains that allowing tests for biomarkers other than albumin and IgG can be useful. The draft OFMG requirements are analogous to the current urine drug testing requirements in that laboratories must perform specified specimen validity tests on all specimens and may perform additional specimen validity tests for other measurands. The Department does not want to limit the testing to albumin and IgG, because other tests or biomarkers may be identified for use. The tests must be forensically acceptable and scientifically sound. Because OF specimen collections are observed and because oral fluid may be collected using a device in which the specimen is diluted by a buffer, a laboratory cannot definitively state that a specimen has been substituted. (The collector or MRO may report a refusal to test as described in Section 1.7 of the OFMG.) As noted in Section 13.5 of the OFMG, when an OF test is reported as Invalid and the donor has no legitimate explanation for the Invalid result, the MRO directs the agency to collect another specimen. The agency may decide the type of specimen for the recollection.

How will oral fluid be collected?

The Department recognizes that methods for collection of oral fluid specimens vary by manufacturers of devices and that new, innovative methods may be developed that offer improvements over existing methods. Two basic types of collection devices currently exist: one is designed to collect undiluted (neat) oral fluid by expectoration; the second type makes use of an absorbent pad that is inserted into the oral cavity for specimen collection and then placed in a tube containing a diluent. The Department is recommending that all collection devices maintain the integrity of the specimen during collection, storage and transport to the laboratory for testing. All devices must have an indicator that demonstrates the adequacy of the volume of collected

specimen; have a sealable, non-leaking container; and have components that ensure pre-analytical drug and drug metabolite stability; and the device components must not substantially affect the composition of drugs and drug metabolites in the oral fluid specimen.

What are the performance requirements for a collection device?

The Department proposes that a collection device should collect either a minimum of 1 mL of undiluted (neat) oral fluid or, for those collection devices containing a diluent (or other component, process, or method that modifies the volume of the specimen), that the volume of oral fluid collected should be within 0.1 mL of the target volume and the volume of diluent in the device should be within 0.05 mL of the diluent target volume. The Department recommends that the device maintain stability of drug and/or drug metabolite in the oral fluid specimen allowing ≥ 90 percent recovery for one week at room temperature (18-25 °C). To ensure that collection device components do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen, the Department recommends that the device performance characteristics are such that there is ≥ 90 percent recovery (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff concentration. The established upper range is to minimize a collection device concentrating the specimen on the collection pad and/or the device. Numerous studies of stability and recovery of drugs from commercial oral fluid collection devices indicate wide variability in performance characteristics.⁵²⁻⁵⁷ The recommended limits of ≥ 90 percent but no more than 120 percent recovery ensure concentration accuracy (within experimental limits), prevent potential concentration of drug and/or metabolite by the device, and ensure consistency in specimen collections using different collection devices.

The Department notes that these collection devices are subject to clearance by the FDA. The Department requests comments on whether HHS should publish a list of FDA-cleared oral fluid collection devices.

What are the collection procedures?

The Department is recommending that a split specimen be collected either 1) as two specimens collected simultaneously or serially with two separate collection devices, or 2) collected with a collection device that subdivides the specimen into two separate collection tubes. If collected serially, collection of the second specimen must begin within two minutes after the completion of the first collection. The Department believes this allows sufficient time for the collector to begin the second specimen collection in a timely manner, to minimize differences in oral fluid collected using two separate collection devices. Oral fluid test results for delta-9-tetrahydrocannabinol (THC) in simultaneously collected specimens with an absorbent pad have been reported to be highly correlated.⁵⁸

In addition, the Omnibus Transportation Employee Testing Act (OTETA), which governs the DOT-regulated testing programs as well as the Federal Aviation Administration's federal employee testing program, requires that collected specimens must be able to be subdivided, to allow for additional testing upon request of the employee.

Therefore, the Department requests comments on whether serial or simultaneous collection using two collection devices constitutes a split collection, and recommendations for any other oral fluid collection processes that enable subdividing the collected specimen.

What new drugs are being included?

Since the late 1980's, multiple recommendations have been made that additional drugs be considered for inclusion in workplace drug testing. These recommendations resulted in the Ecstasy-related drugs – methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA) – being included for testing in 2008. The 2012 National Survey on Drug Use and Health (NSDUH) indicated that past month illicit drug use of psychotherapeutics was second only to marijuana in prevalence among persons aged 12 or older in the United States. Prescription psychotherapeutics include pain relievers, tranquilizers, stimulants, and sedatives.⁵⁹ The abuse of narcotic pain relievers has become a serious and growing public health concern.

Like heroin, many are derived from opium, but are synthetic analogs. Oxycodone and hydrocodone top the list of narcotic pain relievers causing visits to hospital emergency departments due to non-medical use,⁶⁰ and are among the top 10 drugs seized in law enforcement operations and sent to federal, state, and municipal forensic laboratories, ranking second and third of prescription drugs on the list.⁶¹ Because of the prevalence of their abuse, hydrocodone and oxycodone have been included in these proposed OFMG.

Hydrocodone is metabolized in the body to hydromorphone and excreted in biological fluids.⁶² Hydromorphone is also available commercially as an analgesic, is more potent than hydrocodone, and exhibits significant abuse liability. Oxycodone is metabolized in the body to oxymorphone and excreted in biological fluids.⁶³ Oxymorphone is also available commercially as an analgesic, is more potent than oxycodone, and exhibits significant abuse liability. For these reasons, hydromorphone and oxymorphone are also included in these proposed OFMG.

Provisions for the Administration of the National Laboratory Certification Program (NLCP)

In accordance with the current practice, an HHS contractor will perform certain functions on behalf of the Department. These functions include maintaining laboratory inspection and PT programs that satisfy the requirements described in the Guidelines. These activities include, but are not limited to, reviewing inspection reports submitted by inspectors, reviewing PT results submitted by laboratories, preparing inspection and PT result reports, and making recommendations to the Department regarding certification or suspension/revocation of laboratories' certification. It is important to note that, although a contractor gathers and evaluates information provided by the inspectors or laboratories, all final decisions regarding laboratory certification, suspension or revocation of certification are made by the Secretary.

In addition, a contractor has historically collected certain fees from the laboratories for services related to the certification process, specifically for laboratory application and inspection and PT activities for laboratories applying to become HHS-certified, and for inspection and PT activities for laboratories maintaining HHS certification. All fees collected by a contractor are applied to its costs under the contract.

This same process, used since the inception of the laboratory certification program, will also be used by an HHS contractor to collect similar fees from laboratories that seek, achieve, and continue HHS certification to test oral fluid. The Department also contributes funds to this contract for purposes not directly related to laboratory certification activities, such as evaluating technologies and instruments and providing an assessment of their potential applicability to workplace drug testing programs.

Organization of Proposed Guidelines

This preamble describes the differences between the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine Specimens (UrMG) and the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens (OFMG), and provides the rationale for the differences. In addition, the Preamble presents a number of the remaining issues raised during the development of Guidelines for oral fluid drug testing. The issues are organized and presented first in summary as they appear in the text of the proposed OFMG and later as issues of special interest for which the Department is seeking specific public comment.

Subpart A – Applicability

Sections 1.1, 1.2, 1.3, and 1.4 contain the same policies as described in the current UrMG with regard to who is covered by the Guidelines, who is responsible for the development and implementation of the Guidelines, how a federal agency requests a change from these Guidelines and how these Guidelines are revised.

In section 1.5, where terms are defined, the Department proposes to add terms that apply specifically to oral fluid (e.g., collection device, oral fluid specimen).

Sections 1.6, 1.7, and 1.8 contain the same policies as described in the current UrMG with regard to what an agency is required to do to protect employee records, the conditions that constitute refusal to take a federally regulated drug test, and the consequences of a refusal to take a federally regulated drug test.

Subpart B – Oral Fluid Specimen

In section 2.1, the Department proposes to expand the drug-testing program for federal agencies to permit the use of oral fluid specimens. There is no requirement for federal agencies to use oral fluid as part of their program. A federal agency may choose to use urine, oral fluid, or both specimen types in their drug testing program. However, any agency choosing to use oral fluid is required to follow the OFMG. For example, an agency program can randomly assign individuals to either urine or OF testing, for random or pre-employment testing. This would not only help reduce subversion, but would allow comparison of urine and OF testing outcomes for planning purposes.

Section 2.2 describes the circumstances under which an oral fluid specimen may be collected. The Department has included this section to ensure that the circumstances described are consistent with the reasons for collecting a specimen as listed on the Federal Custody and Control Form (Federal CCF). The Department will review comments on the reasons that are appropriate for oral fluid testing.

Section 2.3 describes how each oral fluid specimen is collected for testing. The Department is seeking comment on whether the described procedures are consistent with the established requirement for all specimens to be collected as a split specimen and recommendations for other processes that enable subdividing the collected specimen.

Section 2.4 establishes a known volume that must be collected for each specimen.

Section 2.5 describes how a split oral fluid specimen is collected.

Section 2.6 clarifies that all entities and individuals identified in Section 1.1 of these Guidelines are prohibited from releasing specimens collected under the federal workplace drug testing program to any individual or entity unless expressly authorized by these Guidelines or in accordance with applicable federal law.

While these Guidelines do not authorize the release of specimens, or portions thereof, to federal employees, the Guidelines afford employees a variety of protections that ensure the identity, security and integrity of their specimens from the time of collection through final disposition of the specimen. There are also procedures that allow federal employees to request the retesting of their specimen (for drugs or adulteration) at a different certified laboratory. Furthermore, the Guidelines grant federal employees access to a wide variety of information and records related to the testing of their specimens, including a documentation package that includes, among other items, a copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, and any memoranda generated by the laboratory.

Therefore, the Guidelines offer federal employees and federal agencies transparent and definitive evidence of a specimen's identity, security, control and chain of custody. However, the Guidelines do not entitle employees access to the specimen itself or to a portion thereof. The reason for this prohibition is that specimens collected under the Guidelines are uniquely designed for the purpose of drug and validity testing only. They are not designed for other purposes such as deoxyribonucleic acid (DNA) testing. Furthermore, conducting additional testing outside the parameters of the Guidelines would not guarantee incorporation of the safeguards, quality control protocols, and the exacting scientific standards developed under the Guidelines to ensure the security, reliability and accuracy of the drug testing process.

Subpart C- Oral Fluid Specimen Tests

Section 3.1 describes the tests to be performed on each oral fluid specimen. This is the same policy that is in the current UrMG regarding which drug tests must be performed on a specimen. A federal agency is required to test all specimens for marijuana and cocaine and is

authorized to also test specimens for opiates, amphetamines, and phencyclidine. The Department realizes that most federal agencies typically test for all five drug classes authorized by the existing Guidelines, but has not made this a mandatory requirement, and will continue to rely on the individual agencies and departments to determine their testing needs above the required minimum. The Department included requirements for federal agencies to test all oral fluid specimens for either albumin or IgG to determine specimen validity, but specifically requests public comment on requiring these tests.

The policy in section 3.2 is the same as that for urine testing. Any federal agency that wishes to routinely test its specimens for any drug not included in the Guidelines must obtain approval from the Department before expanding its program. A specimen may be tested for any drug listed in Schedule I or II of the Controlled Substances Act when there is reasonable suspicion/cause to believe that a donor may have used a drug not included in these Guidelines. When reasonable suspicion/cause exists to test for another drug, the federal agency must document the possibility that the use of another drug exists, attach the documentation to the original Federal CCF, and ensure that the HHS-certified laboratory has the capability to test for the additional drug. The HHS-certified laboratory performing such additional testing must validate the test methods and meet the quality control requirements as described in the Guidelines for the other drug analyses.

Section 3.3 states that specimens must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. Additional explanation is provided above, in comments for Section 2.6.

Section 3.4 lists the proposed analytes and cutoff concentrations for undiluted (neat) oral fluid. The table in Section 3.4 specifies both initial and confirmatory cutoff concentrations for

each drug test analyte. Footnote 2 of the table addresses requirements that differ for initial tests using immunoassay-based technology and those using an “alternate” technology. Over the last 5 years, technological advances have been made to techniques (e.g., methods using spectrometry or spectroscopy) that enable their use as efficient and cost-effective alternatives to the immunoassay techniques for initial drug testing while maintaining the required degree of sensitivity, specificity, and accuracy. The proposed Guidelines allow the use of alternate technologies provided that the laboratory validates the method in accordance with Section 11 and demonstrates acceptable performance in the PT program.

Considerable research and discussion were conducted regarding the complex issues surrounding the specification of each cutoff concentration. The Department solicited input from laboratories, reagent and device manufacturers, subject matter experts, and the Food and Drug Administration (FDA). The cutoff concentrations are the outcome of the lengthy discussion process and represent the best approach currently available. The proposed analytes follow:

Marijuana (Cannabis).

The Department is proposing to test for delta-9-tetrahydrocannabinol (THC) using a 4 ng/mL cutoff concentration for the initial test. For the confirmatory test, the Department is proposing to test for THC using a 2 ng/mL cutoff concentration.

Marijuana (cannabis) continues to be the most prevalent drug of abuse in the U.S. THC is the primary psychoactive ingredient of marijuana and is rapidly transferred from the lungs to blood during smoking.⁶⁴ THC is distributed by the blood and absorbed rapidly by body tissues. Apparently, very little unchanged THC is excreted in oral fluid as demonstrated by investigations with intravenously administered THC⁶⁵ or orally administered THC (dronabinol).⁶⁶ The major source of THC in oral fluid occurs from deposition in the mouth during smoking or oral use.⁶⁵

THC appears at its highest concentration in oral fluid immediately after smoking marijuana.^{58, 67,68,69} Initial high concentrations of THC in oral fluid decline rapidly within the first 30 minutes after use and thereafter decline over time in a manner similar to that observed for THC in plasma⁶⁸ and serum.⁷⁰ It has been suggested that the similarity in oral fluid and plasma concentrations can be attributed to a physiological link involving transmucosal THC absorption from oral fluid into blood.¹ One study reported significant correlations of oral fluid THC concentrations with subjective intoxication and with heart rate elevation.⁷¹

Positive prevalence rates for THC in oral fluid specimens collected from workplace drug testing programs appear to be comparable or greater than 11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA) rates for urine drug testing in the general workforce. A 2002 study of 77,218 oral fluid specimens revealed a positive prevalence of 3.22 percent compared to a 3.17 percent positivity rate for more than 5,200,000 urine specimens collected during the same period.⁴⁰ The 2012 Drug Testing Index by Quest Diagnostics for marijuana positivity in the general workforce for oral fluid was 4.0 percent and for urine was 2.0 percent.³⁹

Once absorbed and distributed to tissues, THC is ultimately transformed by oxidative metabolic enzymes to THCA. Further metabolism of THCA leads to formation of a glucuronide metabolite (conjugated metabolite). Both free (unconjugated) THCA⁷²⁻⁷⁴ and conjugated THCA⁷⁵ are excreted in oral fluid in low concentrations (picograms per milliliter). In a study of one frequent marijuana smoker,⁷⁵ concentrations of THC were highest immediately following smoking and declined thereafter. In that study, THC concentrations in oral fluid specimens collected during three different smoking occasions ranged from 0 to 93 ng/mL; free THCA concentrations ranged from 0.027 to 0.085 ng/mL and total (conjugated and free) THCA concentrations ranged from 0.033 to 0.314 ng/mL. The ratio of conjugated THCA to free THCA

ranged from 0.5 to 3.64. Predominantly, there was approximately twice as much conjugated THCA as free THCA in oral fluid specimens, indicating the need for hydrolysis prior to confirmatory analysis to convert conjugated THCA to free THCA, enabling analysis for total THCA. Urine testing programs currently use hydrolysis and test for total THCA, and the analytical procedures for oral fluid are similar to those in practice for urine.

In contrast to urine, there is a paucity of scientific data on the time course of excretion or the detection window of THC, THCA, and conjugated THCA in oral fluid following marijuana use.¹ This is especially true for occasional users. Studies of daily marijuana smokers indicate that THC is detectable for up to two days, but THCA continues to be excreted in oral fluid during abstinence for several weeks in daily users.⁷⁶ As noted earlier, the mechanisms of drug excretion in oral fluid are somewhat different than in urine. Because oral fluid tests generally are positive for parent drug as soon as the drug is administered, the Department, for oral fluid testing, is considering testing and confirming for THC. THC is reliably present in oral fluid immediately after smoked cannabis administration and remains detectable for 24-30 hours or longer, whereas THCA may or may not be present. The risks of passive smoke exposure have been assessed. To date, studies have indicated that transient amounts of THC may be present in oral fluid for a few hours (1-3), and no THCA is detected in oral fluid but is detected in blood. The detection of traces of THC occurred only under conditions of extreme tolerated exposure. Unknowing or transient exposure to marijuana smoke does not appear likely to produce a positive THC test in oral fluid. The Department seeks comment on whether THCA is suitable for inclusion as a reliable test analyte for detection of marijuana use.

The proposed initial test cutoff for THC (4 ng/mL) and confirmatory test cutoff for THC (2 ng/mL) are the same as those proposed in the 2004 Guidelines. The detection time for THC in

oral fluid appears to be shorter than the detection time for THCA in urine;^{58, 67,76,77,78, 79} consequently, a lower initial test cutoff concentration would enhance detection rates of marijuana use. For this reason, the Department is interested in receiving comments on lowering the cutoff concentration for delta-9-tetrahydrocannabinol (THC) to either 2 or 3 ng/mL for the initial test cutoff concentration and to 1 ng/mL for the confirmatory cutoff concentration. Lowering the initial and confirmatory test cutoff concentrations would lengthen the detection window (i.e., the number of hours after a drug is ingested by an individual that the concentration of the drug or drug metabolite in oral fluid will likely be at or above the cutoff concentration). Lower cutoff concentrations will increase the number of specimens that are identified as containing THC and, thereby, will increase the deterrent effect of the program and improve identification of employees using this illicit substance.

The Department had considered proposing to test for THCA (i.e., “total” amount following hydrolysis, as described above) using a 0.050 ng/mL cutoff concentration for confirmation to extend the window of detection. However, the Department is concerned over the utility of confirming for this analyte as well as the ability of laboratories to reliably implement this test for routine analyses, based on the reasons provided below

Currently, few laboratories perform confirmatory testing for THCA in oral fluid testing. Thus, there is limited data on the positivity rates for these analytes in a workplace population. In a study of 143 specimens positive by immunoassay using the proposed 4 ng/mL initial test cutoff,⁷⁴ 84 percent were confirmed positive for THC using the proposed 2 ng/mL confirmatory test cutoff. Only 51 percent would have confirmed positive for THCA using a 0.010 ng/mL cutoff.

Also, testing for THCA requires a larger sample volume than testing for THC. This may affect the ability of a laboratory to perform additional testing as required. To avoid the risk of positive test results from passive exposure, some investigators have recommended that THCA be included in confirmatory testing.^{74,76, 77,78,80} THCA occurs in oral fluid as a result of passive diffusion from blood⁶⁶ and is not found in marijuana smoke.⁸¹ Consequently, the presence of THCA provides evidence of active use of products containing THC (e.g., marijuana, dronabinol). However, based on information provided from recent studies⁸², it does not appear that THCA is reliably present in oral fluid specimens for some marijuana users: a marijuana user's oral fluid specimen may be positive for THC and negative for THCA.

A number of passive exposure studies have been conducted under a variety of exposure conditions.^{58,67,80, 83} Two studies reported that false results for THC were a problem if oral fluid was collected in a contaminated environment.^{67,80} One passive inhalation study in which oral fluid specimens were collected in a clean environment reported no specimens positive for THC at a confirmatory cutoff concentration of 1.5 ng/mL throughout an 8-hour monitoring period following exposure.⁶⁷ A recent study⁸⁰ reported negative results for total THCA at a limit of quantification of 0.002 ng/mL, but found positive results for THC in oral fluid when specimens were collected during three hours of continuous passive exposure. Specimens collected 12 to 22 hours after passive exposure were negative for total THCA and were predominantly negative for THC; however, two of 10 specimens contained detectable amounts of THC (1.0, 1.1 ng/mL) that are well below the proposed 4 ng/mL cutoff for the initial test and 2 ng/mL cutoff for the confirmatory test.

The Department is not aware of any studies that demonstrate passive exposure causing a positive oral fluid THC result when the donor would not be aware of that exposure. Nor does

there appear to be evidence that incidental exposure to marijuana smoke can cause an oral fluid specimen to be reported positive for THC using the proposed cutoff levels. Therefore, passive exposure would not be a reasonable defense for a positive result for THC in oral fluid testing. The Department recognizes that THCA testing may be useful, because THC and THCA may be present singly or in combination in a marijuana user's oral fluid specimen depending on the length of time between use and collection. However, Current technology for conducting a confirmatory test for THCA at pg/mL concentrations requires the use of specialized materials, instrumentation, and methods.^{72,73,84} In addition, a substantial portion of the oral fluid specimen may be consumed in the analytical process, thus making it difficult for a laboratory to confirm multiple initial positive drug tests or reanalyze these specimens. Therefore, the Department is specifically interested in obtaining information on the ability of laboratories to conduct initial and/or confirmatory tests for THCA, as well as the cost of conducting the confirmatory test.

Cocaine

The Department is proposing to test for cocaine/benzoylecgonine using an initial cutoff concentration of 15 ng/mL and 8 ng/mL for the confirmatory cutoff concentrations. Cocaine appears in oral fluid within minutes after use following intravenous, nasal and smoked administration.³⁶ Cocaine is rapidly metabolized to benzoylecgonine that also is excreted in oral fluid. At different times after use, cocaine and benzoylecgonine may be present singly or in combination in oral fluid. The current proposed initial test cutoff for cocaine/benzoylecgonine (15 ng/mL) is lower than that proposed in the 2004 proposed revisions to the Guidelines (20 ng/mL). This change is justified because of the recognition that different combinations of cocaine analytes may be present at different times after use and for enhanced sensitivity for the detection of each analyte.

An immunoassay initial test for cocaine/benzoyllecgonine should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department recommends that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 15 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 8 ng/mL confirmatory test cutoff concentration applies equally to cocaine and benzoyllecgonine. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 8 ng/mL.

Codeine/morphine

The Department is proposing to test for codeine/morphine using a 30 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentrations. After single oral use, codeine has been reported to appear in oral fluid within an hour, quickly reach maximum concentration and decline over a period of approximately 24 hours.⁸⁵ An earlier study showed that codeine appeared in urine within an hour of dosing, and was detectable up to four days.⁸⁶ A metabolite of codeine, norcodeine, was also detected in oral fluid, but morphine was not detected. Although there is high variability, codeine oral fluid concentrations have been significantly correlated with plasma codeine concentrations.^{85,87} Codeine undergoes extensive metabolism in the body. Two important, but minor metabolites of codeine are morphine and hydrocodone.^{88,89,90} Morphine may be present in oral fluid as a result of administration of morphine,^{91,92} heroin,³⁵ or ingestion of poppy seeds.³⁷ A study of morphine

levels in urine and oral fluid following ingestion of poppy seeds indicated that morphine was positive for a shorter period of time (approximately 2 hours) compared to urine (approximately 8 hours).³⁷ A study of 77,218 oral fluid specimens collected under workplace drug testing conditions indicated that approximately 12.5 percent of specimens positive for morphine or codeine were positive in the concentration range of 30 to 39.9 ng/mL and would have been reported negative using a 40 ng/mL confirmatory cutoff concentration.⁴⁰ The current proposed initial test cutoff concentration (30 ng/mL) and confirmatory test cutoff concentration (15 ng/mL) for codeine/morphine are lower than those in the 2004 proposed revisions to the Guidelines (40 ng/mL for initial test and confirmatory test), primarily due to the enhanced sensitivity especially for the detection of morphine.

An immunoassay initial test for codeine/morphine should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department proposes that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 30 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 15 ng/mL confirmatory test cutoff concentration applies equally to codeine and morphine. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 15 ng/mL.

6-Acetylmorphine

The Department is proposing to test for 6-acetylmorphine using a 3 ng/mL cutoff concentration for the initial test and 2 ng/mL for the confirmatory test cutoff concentration. 6-acetylmorphine, a unique metabolite of heroin, appears in oral fluid within minutes following smoked or injected heroin administration.³⁵ A high prevalence of 6-acetylmorphine in oral fluid specimens following heroin use has been reported,⁹³⁻⁹⁶ suggesting it may offer advantages over urine in workplace testing programs. An initial assay for 6-acetylmorphine separate from a general opiates assay is currently used in the UrMG. The 2004 proposed revisions to the Guidelines did not propose a separate initial test for 6-acetylmorphine. An initial test for 6-acetylmorphine is proposed because of the recent recognition that 6-acetylmorphine may be positive in oral fluid specimens that would not initially test positive for opiates.^{35,94} A study of 77,218 oral fluid specimens collected under workplace drug testing conditions indicated that 12.5 percent of specimens positive for 6-acetylmorphine were positive in the concentration range of 3 to 3.9 ng/mL and would have been reported negative at a 4 ng/mL confirmatory cutoff concentration.⁴⁰ The current proposed confirmatory test cutoff concentration (2 ng/mL) for 6-acetylmorphine is lower than in the 2004 proposed revisions to the Guidelines (4 ng/mL), primarily for enhanced sensitivity.

Phencyclidine

The Department is proposing to test for phencyclidine using a 3 ng/mL cutoff concentration for the initial test and 2 ng/mL for the confirmatory test cutoff concentration. Phencyclidine has been measured in oral fluid following different routes of administration.^{97,98} A study of 77,218 oral fluid specimens collected under workplace drug testing conditions indicated that 57.1 percent of specimens positive for phencyclidine were positive in the concentration range of 1.5 to 9.9 ng/mL and would have been reported negative at a 10 ng/mL

confirmatory cutoff concentration.⁴⁰ The current proposed initial test cutoff concentration (3 ng/mL) and confirmatory test cutoff concentration (2 ng/mL) for phencyclidine are lower than those in the 2004 proposed revisions to the Guidelines (10 ng/mL for initial test and confirmatory test), primarily for enhanced sensitivity.

Amphetamine/methamphetamine

The Department is proposing to test for amphetamine/methamphetamine using a 25 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentration. Amphetamine appears rapidly in oral fluid following administration⁹⁹ and, although variable, correlates with blood concentrations in drivers suspected of driving under the influence of drugs.¹⁰⁰ Methamphetamine and its metabolite, amphetamine, also appear rapidly in oral fluid and plasma following administration.^{101,102} In one study,¹⁰² concentrations of amphetamine relative to methamphetamine in oral fluid ranged from 16 percent to 37 percent following methamphetamine administration. The positivity rate for methamphetamine in oral fluid was highly influenced by the requirement for detection of amphetamine metabolite in the study. When the confirmatory cutoff concentration for methamphetamine was 50 ng/mL and detection of amphetamine at 2.5 ng/mL (limit of detection) was applied to oral fluid specimens, only 1 of 13 individuals tested positive 24 hours after a single methamphetamine dose and; only 23 of 130 (18 percent) specimens tested positive within 24 hours after dosing. The current proposed initial test cutoff concentration (25 ng/mL) and confirmatory test cutoff concentration (15 ng/mL) for amphetamine/methamphetamine are lower than those in the 2004 proposed revisions to the Guidelines (50 ng/mL for initial test and confirmatory test), primarily for enhanced sensitivity. There is no proposed reporting requirement for a methamphetamine-positive specimen to contain amphetamine as there is in the UrMG.

An immunoassay initial test for amphetamine/methamphetamine should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department recommends that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 25 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 15 ng/mL confirmatory test cutoff concentration applies equally to amphetamine and methamphetamine. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 15 ng/mL.

Methylenedioxymethamphetamine (MDMA)/Methylenedioxyamphetamine (MDA)/Methylenedioxyethylamphetamine (MDEA)

The Department is proposing to test for MDMA/MDA/MDEA using a 25 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentration. MDMA appears in oral fluid approximately 0.25-1.5 hours following oral administration and demonstrates similar kinetic patterns as plasma concentrations.¹⁰³⁻¹⁰⁵ MDMA is metabolized by N-demethylation to MDA, a compound that exhibits similar psychoactive properties to MDMA. As a metabolite of MDMA, MDA is excreted in oral fluid with concentrations representing approximately 4-5 percent of MDMA.¹⁰⁴ MDEA also is metabolized by N-dealkylation to MDA as an active metabolite.¹⁰⁶ MDEA has been reported in oral fluid specimens collected from recreational drug users in concentrations ranging from 25 to 3320 ng/mL.¹⁰⁵ The current recommended initial test concentration (25 ng/mL) and confirmatory test cutoff concentration

(15 ng/mL) for MDMA/MDA/MDEA are lower than those in the 2004 proposed revisions to the Guidelines (50 ng/mL for initial test and confirmatory test), primarily for enhanced sensitivity.

An immunoassay initial test for MDMA/MDA/MDEA should be calibrated with one of the three analytes and demonstrate sufficient cross-reactivity with each analyte. The Department recommends that the minimum cross-reactivity with each analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or all analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the three analytes must be equal to or greater than 25 ng/mL. The quantitative sum of the three analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 15 ng/mL confirmatory test cutoff concentration applies equally to MDMA, MDA and MDEA. A positive test would be comprised of one or more of the three analytes with a confirmed concentration equal to or greater than 15 ng/mL.

Inclusion of Oxycodone, Oxymorphone, Hydrocodone, Hydromorphone

Misuse and abuse of psychotherapeutic prescription drugs, including opioid pain relievers, are issues of concern for all populations regardless of age, gender, ethnicity, race, or community. Recent data show that opioid-related overdose deaths in the U.S. now outnumber overdose deaths involving all illicit drugs such as heroin and cocaine combined. In addition to overdose deaths, emergency department visits, substance abuse treatment admissions, and economic costs associated with opioid abuse have all increased in recent years. The Department is continuing to work with partners at the federal, state, and local levels to implement policies and programs to reduce prescription drug abuse and improve public health.¹⁰⁷

The Department proposes the inclusion of additional Schedule II prescription medications (i.e., oxycodone, oxymorphone, hydrocodone and hydromorphone) in the list of authorized drug tests and cutoff concentrations. This action was recommended by the DTAB, reviewed by the Department's Prescription Drug Subcommittee of the Behavioral Health Coordinating Committee, and received by the SAMHSA Administrator in January 2012. The inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone is supported by various data. According to the 2012 National Survey on Drug Use and Health, which provides data on illicit drug use in the U.S., current (past month) nonmedical users aged 12 years and older of prescription psychotherapeutic drugs increased from 2003 (6.5 million) to 2012 (6.8 million).⁵⁹ Psychotherapeutic drugs are defined as opioid pain relievers, tranquilizers, sedatives, and stimulants. The abuse of psychotherapeutic drugs non-medically is ranked second behind marijuana, where pain relievers represent the majority of the group. The Drug Abuse Warning Network (DAWN) Report, which provides national estimates of drug-related visits to hospital emergency departments (ED), showed that of the 1.2 million ED visits involving nonmedical use of pharmaceuticals in 2011, 46.0 percent of visits involved nonmedical use of pain relievers, with 29 percent being narcotic pain relievers.⁶⁰ The most frequently involved narcotic pain relievers were oxycodone and hydrocodone. From 2004 to 2011, ED visits involving nonmedical use of narcotic pain relievers increased by 153 percent. ED visits involving opiates/opioids increased by 183 percent during this period, with increases of 438 percent for hydromorphone, 263 percent for oxycodone, and over 100 percent for hydrocodone, as well as fentanyl and morphine. In addition, the National Forensic Laboratory Information System (NFLIS) found that oxycodone and hydrocodone were among the top ten drugs seized in law enforcement operations and sent to federal, state, and municipal forensic laboratories.⁶¹ Among

prescription drugs, oxycodone and hydrocodone ranked first and second. Information on over 5 million drug tests in general workplace drug testing shows that the positivity rate for oxycodone and hydrocodone (0.96%) was second only to marijuana in 2012.³⁹

The use of medications, specifically Schedule II drugs, without a prescription is a growing concern for the Department in workplace drug testing, and the proposal for their inclusion offers the opportunity to deter nonmedical use of these drugs among federal workers. The Department does note that in recognition of the prescription drug abuse issue, the Department of Defense issued a memorandum on January 30, 2012, announcing the expansion of their drug testing panel to include hydrocodone and benzodiazepines starting on May 1, 2012. Similarly, the Department proposes that federal agencies include the testing of oxycodone, oxymorphone, hydrocodone, and hydromorphone in oral fluid specimens as described below.

Oxycodone/oxymorphone

The Department is proposing to test for oxycodone/oxymorphone using a 30 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentrations. Both oxycodone and oxymorphone have been reported to be readily detectable in oral fluid specimens collected from pain patients.^{41,108} Oxycodone is metabolized in relatively minor amounts to oxymorphone.⁶³ Oxymorphone is a potent analgesic used for pain relief orally and parenterally, and is primarily metabolized by conjugation.¹⁰⁹

An immunoassay initial test for oxycodone/oxymorphone should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department recommends that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The

quantitative sum of the two analytes must be equal to or greater than 30 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 15 ng/mL confirmatory test cutoff concentration applies equally to oxycodone and oxymorphone. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 15 ng/mL.

Hydrocodone/hydromorphone

The Department is proposing to test for hydrocodone/hydromorphone using a 30 ng/mL cutoff concentration for the initial test and 15 ng/mL for the confirmatory test cutoff concentration. Hydromorphone appears rapidly in oral fluid following intravenous administration and follows a similar kinetic profile as that observed in plasma.¹¹⁰ Both hydrocodone and hydromorphone have been reported to be readily detectable in oral fluid specimens collected from pain patients.^{41,108} Hydrocodone is metabolized in relatively minor amounts to hydromorphone.⁶² Hydromorphone is a potent analgesic used for pain relief orally and parenterally, and is primarily metabolized by conjugation.¹¹¹ Hydrocodone has been reported to be a minor metabolite of codeine⁹⁰ and hydromorphone has been reported to be a minor metabolite of morphine.^{112,113}

An immunoassay initial test for hydrocodone/hydromorphone should be calibrated with one of the two analytes and demonstrate sufficient cross reactivity with the other analyte. The Department proposes that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 30 ng/mL. The quantitative

sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The confirmatory test cutoff concentration applies equally to hydrocodone and hydromorphone. A positive test would be comprised of either or both analytes with a confirmed equal to or greater than 15 ng/mL.

In 2009, the U.S. Drug Enforcement Administration (DEA) asked the U.S. Department of Health and Human Services (HHS) for a recommendation regarding whether to change the schedule for hydrocodone combination drug products, such as Vicodin. The proposed change was from Schedule III to Schedule II, which would increase the controls on these products. Due to the unique history of this issue and the tremendous amount of public interest, in October 2013, the FDA Center for Drug Evaluation and Research announced the agency's intent to recommend to HHS that hydrocodone combination drug products should be reclassified to Schedule II. FDA stated that this determination came after a thorough and careful analysis of extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings, during which FDA received input from a wide range of stakeholders, including patients, health care providers, outside experts, and other government entities.

In December 2013, FDA, with the concurrence of the National Institute on Drug Abuse (NIDA), submitted a formal recommendation package to HHS to reclassify hydrocodone combination drug products into Schedule II. Also in December 2013, the Secretary of HHS submitted the scientific and medical evaluation and scheduling recommendation to the DEA for its consideration. On August 22, 2014, DEA published the Final Rule that moves hydrocodone combination drug products from Schedule III to Schedule II.

Section 3.5 authorizes HHS-certified laboratories to perform additional tests to assist the MRO in making a determination of positive or negative results. The Department believes that additional tests can be requested by the MRO to further inform them to determine the veracity of the medical explanation of the donor. An example of an additional test currently requested by an MRO is when the laboratory reports a positive methamphetamine result. The MRO may request a d,l-stereoisomer determination for methamphetamine, to determine whether the result could be attributed to use of an over-the-counter nasal inhaler. Another example of current practice is when the laboratory reports a positive THCA result, and the MRO requests testing for cannabivarin, to distinguish marijuana use from dronabinol (e.g., Marinol®).

Section 3.6 includes criteria for reporting an oral fluid specimen as adulterated. While there are no known oral fluid adulterants at this time, the Department is proposing to establish criteria similar to that for urine specimens, to ensure procedures that are forensically acceptable and scientifically sound, while allowing laboratories the flexibility necessary to develop specific testing requirements for an adulterant.

Section 3.7 incorporates criteria from the UrMG that are applicable for reporting an invalid result for an oral fluid specimen, and includes an additional criterion to enable laboratories to perform specimen validity testing using biomarkers other than IgG and albumin.

Subpart D - Collectors

Sections 4.1 through 4.5 contain the same policies as described in the current UrMG in regard to who may or may not collect a specimen, the requirements to be a collector, the requirements to be a trainer for collectors, and what a federal agency must do before a collector is permitted to collect a specimen.

Subpart E - Collection Sites

Sections 5.1 through 5.5 address requirements for collection sites, collection site records, how a collector ensures the security and integrity of a specimen at the collection site, and the privacy requirements when collecting a specimen.

Subpart F - Federal Drug Testing Custody and Control Form

Sections 6.1 and 6.2 are the same as in the current UrMG, requiring an OMB-approved Federal CCF be used to document custody and control of each specimen at the collection site, and specifying what should occur if the correct OMB-approved CCF is not used.

Subpart G – Oral Fluid Specimen Collection Devices

Section 7.1 describes the type of collection device that must be used to collect an oral fluid specimen. A single use device that has been cleared by the FDA for the collection of oral fluid must be used.

Section 7.2 describes specific requirements for the oral fluid collection device, to ensure that the device provides a sufficient volume for laboratory analysis and maintains the integrity of the specimen. The Department has determined that it is essential that the device have a volume adequacy indicator showing that a minimum volume of 1 mL oral fluid has been collected; that the container be sealable and non-leaking; and that all components of the device ensure drug and metabolite stability and do not substantially affect the composition of drug and/or drug metabolites in the specimen.

Section 7.3 details the minimum performance requirements for a collection device. Considering the variety of oral fluid collection devices available, the Department considers it necessary to require that any device used meet minimum standards to ensure the integrity of the specimen and the standardization of the laboratory analysis process.

Subpart H – Oral Fluid Specimen Collection Procedure

This subpart addresses the same topics, in the same order, as the UrMG procedures for urine specimen collection.

Section 8.1 specifies the procedures required to provide privacy for the oral fluid donor during the collection procedure.

Sections 8.2 through 8.5 describe the responsibilities and procedures the collector must follow before, during, and after an oral fluid collection.

Section 8.6 describes the procedures the collector must follow when a donor is unable to provide an oral fluid specimen.

Section 8.7 prohibits collection of an alternate specimen when a donor is unable to provide an adequate oral fluid specimen, unless specifically authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs and by the federal agency.

Section 8.8 describes how the collector prepares the oral fluid specimens, including the description of the oral fluid split specimen collection.

Section 8.9 specifies how a collector is to report a refusal to test.

Section 8.10 is the same as that in the UrMG in regard to federal agency responsibilities for ensuring that each collection site complies with all provisions of the Mandatory Guidelines. An example of appropriate action that may be taken in response to a reported collection site

deficiency is self-assessment using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs. This document will be available on the SAMHSA website <http://www.samhsa.gov/workplace/drug-testing>.

Subpart I – HHS-Certification of Laboratories

This subpart addresses the same topics for HHS certification of laboratories to test oral fluid specimens, as are included in the UrMG for HHS certification of laboratories to test urine specimens.

Sections 9.1 through 9.4 contain the same policies as in the current UrMG for laboratories to become HHS-certified and to maintain HHS certification to conduct oral fluid testing for a federal agency, as well as what a laboratory must do when certification is not maintained.

Section 9.5 contains specifications for PT samples, Section 9.6 contains PT requirements for an applicant laboratory, and Section 9.7 contains PT requirements for an HHS-certified laboratory. These sections incorporate the applicable requirements from the current UrMG, but exclude UrMG requirements that are specific for urine testing and include those specific for oral fluid testing.

The remaining Sections 9.8 through 9.17 contain the same policies as the UrMG. These sections address inspection requirements for applicant and HHS-certified laboratories, inspectors, consequences of an applicant or HHS-certified laboratory failing to meet PT or inspection performance requirements, factors considered by the Secretary in determining the revocation or suspension of HHS-certification, the procedure for notifying a laboratory that

adverse action (e.g., suspension or revocation) is being taken by HHS, and the process for re-application once a laboratory's certification has been revoked by the Department.

Section 9.17 states that a list of laboratories certified by HHS to conduct forensic drug testing for federal agencies will be published monthly in the Federal Register. The list will indicate the type of specimen (e.g., oral fluid or urine) that each laboratory is certified to test.

Subpart J - Blind Samples Submitted by an Agency

This subpart (Sections 10.1 through 10.4) describes the same policies for federal agency blind samples as the UrMG, with two exceptions. Oral fluid blind samples that challenge specimen validity tests are not required, and the blind supplier must validate blind samples in the selected manufacturer's collection device.

Subpart K - Laboratory

This subpart addresses the same topics, in the same order, as the UrMG procedures for laboratories testing urine specimens. As appropriate, the section includes requirements that are specific for oral fluid testing.

Sections 11.1 through 11.8 include the same requirements that are contained in the current UrMG for the laboratory standard operating procedure (SOP) manual; responsibilities and scientific qualifications of the responsible person (RP); procedures in the event of the RP's extended absence from the laboratory; qualifications of the certifying scientists, certifying technicians, and other HHS-certified laboratory staff; security; and chain of custody requirements for specimens and aliquots.

Sections 11.9 through 11.14 include the same requirements as in the current UrMG in regard to initial and confirmatory drug test requirements, validation, and batch quality control as described in each section below.

Section 11.9 describes the requirements for the initial drug test which permit the use of an immunoassay or alternate technology (e.g., spectrometry or spectroscopy). The Department believes that new technology has advanced in the initial testing for drugs, and does not want to limit the testing technology to immunoassay.

Sections 11.10 and 11.11 cover validation and quality control requirements for the initial test.

Section 11.12 describes the requirements for a confirmatory drug test. The Department proposes to allow analytical procedures using mass spectrometry or other equivalent technologies. Based on ongoing reviews of the scientific and forensic literature, and the assessment of a DTAB working group that has studied newer instruments and technologies, the Department believes that scientifically valid confirmatory methods other than combined chromatographic and mass spectrometric methods can be used to successfully detect and report the cutoff concentrations proposed in Subpart C-Oral Fluid Specimen Drug Tests.

Sections 11.13 and 11.14 cover validation and quality control requirements for the confirmatory tests.

Sections 11.15 and 11.16 address specimen validity tests that a laboratory performs for oral fluid specimens. The Department included requirements in the OFMG to test all specimens for albumin or IgG and to allow laboratories to perform other specimen validity tests. All specimen validity tests must use appropriate analytical methods that are properly controlled and validated, to provide scientifically supportable and forensic acceptable results to the MRO.

Section 11.17 describes in detail how a certified laboratory is required to report test results to MRO for oral fluid specimens.

Sections 11.18 and 11.19 contain the same requirements as the UrMG for specimen and record retention.

Section 11.20 describes the statistical summary report that a laboratory must provide to a federal agency for oral fluid testing. This section is comparable to the same section in the UrMG, differing only in that the statistical report elements are specific for oral fluid testing.

Section 11.21 addresses the laboratory information to be made available to a federal agency and describes the contents of a standard laboratory documentation package. This is the same policy as in the UrMG.

Section 11.22 addresses the laboratory information to be made available to a federal employee upon written request through the MRO, and clarifies that specimens are not a part of the information package that donors can receive from HHS-certified laboratories. This is the same policy as in the UrMG.

The remaining section, Section 11.23, describes the relationships that are prohibited between an HHS-certified laboratory and an MRO. These are the same as in the UrMG.

Subpart L – Instrumented Initial Test Facility (IITF)

This subpart emphasizes that federal agencies may choose to use IITFs for urine testing but not for oral fluid testing. Section 12.1 clearly states that only HHS-certified laboratories are authorized to test oral fluid specimens for federal agency workplace drug testing programs.

Instrumented Initial Test Facilities are not practical and will not be allowed due primarily to the limited sample volume of oral fluid collected from the donor.

Subpart M - Medical Review Officer (MRO)

This subpart addresses the same topics, in the same order, as the UrMG procedures for Medical Review Officers (MROs).

Section 13.1 describes who may serve as an MRO. With the inclusion of additional Schedule II prescription medications in the Mandatory Guidelines and the ever-changing field of drug testing, medical review of drug test results is more complex today than before. Therefore, the Department proposes to incorporate MRO requalification training and reexamination on a regular basis (at least every five years). The URMG and OFMG do not include a requirement for MROs to obtain continuing education units (CEUs). The Department understands that it would be difficult to determine whether CEUs obtained are related to federal agency drug testing. The requalification requirement every five years will assure agency auditors and inspectors and regulated employers that MROs are appropriately qualified. This requirement is not expected to increase costs to MROs. Current practices for MRO requirements have equivalent standards but vary among MRO training entities. These requirements will standardize the length of time each MRO is required to take a requalification examination. Currently, some MRO requalification periods are longer than five years, while others are less than five years. The Department assumes that the costs to those MROs that have requalification periods over five years will be offset by the cost savings to MROs that have periods shorter than five years. Thus, the Department has not estimated any costs associated with this provision, but it welcomes comment on this assumption.

The Department anticipates that MROs will continue to obtain CEUs by virtue of maintaining their medical licensure requirements. In addition, the MRO certification/training

entities provide MRO manuals and periodic newsletters with updates on federal drug testing program requirements. However, the Department is seeking comments on requiring MRO requalification CEUs and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required as part of MRO requalification.

MROs play a key role in the federal safety program and maintain the balance between the safety and privacy objectives of the program. The MRO's role in gathering and evaluating the medical evidence and providing due process is imperative. These are duties that must be carried out by the MRO and cannot be delegated to other personnel who are not certified by an MRO entity.

The MRO is charged with certain important medical and administrative duties. The MRO must have detailed knowledge of the effects of medications and other potential alternative medical explanations for laboratory reported drug test results. He or she is responsible for determining whether legitimate medical explanations are available to explain an employee's drug test result. This medical review process has become far more complex as a result of specimen validity testing and the myriad of medical explanations for adulterated, substituted, and invalid laboratory test results. These complexities have made MRO knowledge of the effects of drugs and medications even more important.

In addition, MROs confer with prescribing physicians in making decisions about prescription changes so that alternative medications can be used that will not impact public safety. Similarly, the MRO is required to report to employers the employees' prescription and over-the-counter medication use (or dangerous combinations of use) that the MRO believes will negatively affect duty performance. In addition, the MRO is required to medically assess referral physician examinations and evaluations in certain positive and refusal-to-test situations.

These, too, have become more complex over time.

Section 13.2 describes how nationally recognized entities or subspecialty boards that certify MROs are approved.

Section 13.3 describes the training that is required before a physician may serve as an MRO. The Department has added a requirement for MRO training to include information about how to discuss substance misuse and abuse and how to access those services. MROs performing the review of federal employee drug test results should be aware of prevention and treatment opportunities for individuals and can provide information to the donor.

Section 13.4 describes the responsibilities of an MRO.

Section 13.5 describes an MRO's actions when reviewing an oral fluid specimen's test results. This section includes procedures that are specific to oral fluid specimen results.

In Section 13.5, item c(2)(ii), the Department proposes a morphine or codeine confirmatory concentration that the MRO verifies as positive without requiring clinical evidence of illegal drug use, when the donor does not have a legitimate medical explanation. As in the UrMG, this section states that the MRO must not consider consumption of food products as a legitimate explanation for the donor having morphine or codeine at or above the specified concentration in his or her oral fluid. There is limited information in the scientific literature on the codeine and/or morphine concentrations seen in oral fluid after consumption of poppy seed food products. Therefore, the Department is proposing a conservative concentration of 150 ng/mL (i.e., 10 times the confirmatory test cutoff) as the decision point. The Department specifically requests public comment on the appropriateness of this concentration.

Section 13.6 describes what an MRO must do when the collector reports that a donor did not provide a sufficient amount of oral fluid for a drug test. This section contains the same

procedures as the UrMG, with information specific to oral fluid specimens.

Section 13.7 describes what an MRO must do when a donor has a permanent or long-term medical condition that prevents him or her from providing a sufficient amount of oral fluid for a federal agency applicant/pre-employment, follow-up, or return-to-duty test. These procedures are the same as in the UrMG.

The remaining sections, Sections 13.8, 13.9, and 13.10, are the same as in the UrMG, addressing who may request a test of the split (B) specimen, how an MRO reports a primary (A) specimen result, and the types of relationship that are prohibited between an MRO and an HHS-certified laboratory.

Subpart N - Split Specimen Tests

Sections 14.1 and 14.2 include the same policies as the UrMG in regard to when a split (B) specimen may be tested and the testing requirements for a split specimen when the primary specimen was reported positive for a drug(s).

Section 14.3 specifies how the split testing laboratory tests a split (B) oral fluid specimen when the primary (A) specimen was reported as adulterated. As noted previously in this Preamble, the Department is not aware of any adulterants being used for oral fluid specimens, but has included policies in these Guidelines to allow for the testing and reporting of adulterants in oral fluid.

Section 14.4 includes the same policy as the UrMG, requiring the laboratory to report the split (B) specimen result to the MRO.

In Section 14.5, the Department is proposing the actions an MRO must take after receiving the split (B) specimen result. This section is analogous to the corresponding section in the UrMG, with differences where applicable for oral fluid specimen reports.

Section 14.6 is the same as the UrMG in regard to how an MRO reports a split (B) specimen result to an agency.

Section 14.7 is the same as the UrMG, requiring the HHS-certified laboratory to retain a split oral fluid specimen for the same length of time that the primary specimen is retained.

Subpart O – Criteria for Rejecting a Specimen for Testing

Sections 15.1 and 15.2 contain the same policies as the current UrMG for discrepancies requiring a laboratory to reject a specimen and for discrepancies that require a laboratory to reject a specimen unless the discrepancy is corrected.

Section 15.3 lists those discrepancies that would not affect either testing or reporting of an oral fluid specimen result. These are similar to the corresponding section in the UrMG, with differences where applicable for oral fluid specimens.

Section 15.4 describes the discrepancies that may require the MRO to cancel a test, which are the same as those in the UrMG.

Subpart P - Laboratory Suspension/Revocation Procedures

In this subpart, the Department proposes the same procedures that are described in the UrMG to revoke or suspend the HHS-certification of laboratories.

Impact of These Guidelines on Government Regulated Industries

The Department is aware that these proposed new Guidelines may impact the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) regulated industries depending on these agencies' decisions to incorporate the final OFMG into their programs under their own authority.

Topics of Special Interest

The Department requests public comment on all aspects of this notice. However, the Department is providing the following list of areas for which specific comments are requested.

Section 3.1 requires federal agencies to test all oral fluid specimens for either albumin or IgG to determine specimen validity. The Department specifically requests public comment on this requirement.

Section 3.4 lists the proposed cutoff concentrations. The Department is specifically requesting comments on the appropriateness of these proposed cutoffs.

Regarding Section 3.4, the Department is specifically interested in obtaining information on the capability of laboratories to test THCA analyte using a cutoff of 50 pg/mL and the validity of whether THCA can be established as an accurate, sensitive and valid marker for oral fluid testing to detect marijuana use. Additionally, the Department is interested in obtaining information whether THCA should be used to extend the window of detection of marijuana use. The Department is also interested in receiving comments on lowering the cutoff concentration for delta-9-tetrahydrocannabinol (THC) to either 2 or 3 ng/mL for the initial test cutoff concentration and to 1 ng/mL for the confirmatory cutoff concentration to extend the window of detection.

In section 7.3, the Department proposes performance requirements for a collection device. The Department is requesting specific comments on these requirements.

In Section 13.5, the Department proposes a concentration of 150 ng/mL morphine or codeine be used by the MRO to report a positive result in the absence of a legitimate medical explanation (i.e., prescription), without requiring clinical evidence of illegal opiate use, and to rule out the possibility of a positive result due to consumption of food products. The Department is requesting specific comments on this proposed concentration.

Regulatory Impact and Notices

The Department welcomes public comment on all figures and assumptions described in this section.

Executive Orders 13563 and 12866

Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review) states “Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.” Consistent with this mandate, Executive Order 13563 requires agencies to tailor “regulations to impose the least burden on society, consistent with obtaining regulatory objectives.” Executive Order 13563 also requires agencies to “identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice” while selecting “those approaches that maximize net benefits.” This notice proposes a regulatory approach that will reduce burdens to

providers and to consumers while continuing to provide adequate protections for public health and welfare.

The Secretary has examined the impact of the proposed Guidelines under Executive Order 12866, which directs federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). In addition, the Department published a Federal Register notice in June 2011 to solicit comments regarding the science and practice of oral fluid testing via a Request for Information (RFI) [76 FR 34086].

According to Executive Order 12866, a regulatory action is “significant” if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. The proposed Guidelines do establish additional regulatory requirements and allow an activity that was otherwise prohibited. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for “a matter relating to agency management or personnel” 5 U.S.C. § 553(a)(2). Because the Guidelines issued by the Secretary govern federal workplace drug testing programs, HHS has taken the position that the Guidelines are a “matter relating to agency management or personnel” and, thus, are not subject to the APA’s requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs.

Need for regulation

Enhances Flexibility

The proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) will provide flexibility to address workplace drug testing needs of federal agencies while continuing to promulgate established standards to ensure the full reliability and accuracy of drug test results.

Enhances Versatility

Medical conditions exist that may prevent a federal employee or applicant from providing sufficient urine or oral fluid for a drug test. When the OFMG are implemented, in the event that an individual is unable to provide a urine specimen, the federal agency may authorize the collection of an oral fluid specimen. In the event a federal agency adopts oral fluid testing and the donor is unable to collect an oral fluid specimen, the federal agency may also authorize the collection of a urine specimen. This will reduce both the need to reschedule collections and the need for the Medical Review Officer (MRO) to arrange a medical evaluation of a donor's inability to provide a specimen.

Urine collection requires use of a specialized collection facility, secured restrooms, the same gender, and other special requirements. Oral fluid may be collected in various settings. An acceptable oral fluid collection site must allow the collector to observe the donor, maintain control of the collection device(s) during the process, maintain record storage, and protect donor privacy.

Decreases Invalid Tests

Oral fluid collections will occur under observation, which should substantially lessen the risks of specimen substitution and adulteration that has been associated with urine specimen

collections, most of which are unobserved. All oral fluid specimens will be tested for either albumin or immunoglobulin G (IgG) to identify invalid specimens.

Saves Time

Oral fluid collection can require less time than urine collection, reducing employee time away from the workplace and, therefore, reducing costs to the federal agency employer. Oral fluid collection does not require a facility that provides visual privacy during the collection. It is expected that many oral fluid collections will occur at or near the workplace, and not at a dedicated collection site, thereby reducing the amount of time away from the workplace. The collector is allowed to be in the vicinity of the donor, reducing the loss of productive time. The option to collect a urine specimen in the event that the donor cannot provide an oral fluid specimen (and vice versa) will reduce both the need to reschedule a collection and the need for the MRO to arrange a medical evaluation of a donor's inability to provide a specimen.

Administrative data indicates it takes, on average, about 4 hours from the start of the notification of the drug test to the actual time a donor reports back to the worksite. Since oral fluid collection does not have the same privacy concerns as urine collection, onsite collections are likely, thereby reducing the time a donor is away from the worksite. The Department estimates the time savings to be between 1 and 3 hours. This range reflects uncertainty around the location of the collection. The lower bound represents an estimate of time savings if the collection was conducted at an offsite location. The upper bound estimate represents the time savings if the collection was conducted at the employee's workplace, and thus incorporates travel time savings. Using OPM's estimate for the average annual salary of Federal employees converted to an

hourly wage, the savings generated for the Federal Government would be roughly \$400,000 to \$1.2 million a year, or \$38 to \$114 per test.

Versatility in Detection

The time course of drugs and metabolites differs between oral fluid and urine, resulting in some differences in analytes and detection times. Oral fluid tests generally are positive as soon as the drug is absorbed into the body. In contrast, urine tests that are based solely on detection of a metabolite are dependent upon the rate and extent of metabolite formation. Thus, oral fluid may permit more interpretative insight into recent drug use drug-induced effects that may be present shortly before or at the time the specimen is collected. A federal agency may select the specimen type for collection based on the circumstances of the test. For example, in situations where drug use at the work-site is suspected, the testing of oral fluid may show the presence of an active drug, which may indicate recent administration of the drug and be advantageous when assessing whether the drug contributed to an observed behavior.

Advances in Oral Fluid Drug Testing

In the past, urine was the only permitted specimen for forensic workplace drug testing. However, some issues that previously deterred the use of oral fluid for drug testing have been resolved. The scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established. For example, oral fluid collection devices and procedures have been developed that protect against biohazards, maintain the stability of analytes, and provide sufficient oral fluid for testing. In addition, OFMG analyte cutoff concentrations are much lower than those specified for urine in the Guidelines. Additionally, specimen volume is

also much lower, saving time in collection and transport cost. Developments in analytical technologies have allowed their use as efficient and cost-effective methods that provide the needed analytical sensitivity and accuracy for testing oral fluid specimens.

Current Testing in the Drug Free Workplace Program

Urine was the original specimen of choice for forensic workplace drug testing, and urine testing is expected to remain an established and reliable component of federal workplace drug testing programs. Urine testing provides scientifically accurate and legally defensible results and has proven to be an effective deterrent to drug use in the workplace.

A major challenge to urine drug testing has been the proliferation of commercial products used to adulterate or substitute a donor's urine specimen. Due to individual privacy rights, most urine collections are unobserved, allowing the opportunity to use such products. As the Department has established requirements and laboratories have developed procedures to control for adulterated and substituted specimens, manufacturers have developed new products to avoid detection. Current research indicates that some current substitution products are indistinguishable from human urine. The use of these products is expected to continue.

Time Horizon of this Analysis

The transition to the testing of oral fluids will be gradual and steady over the course of four years, when it should plateau. By this time, it is expected that oral fluid tests will account for 25-30% of all regulated drug testing. This estimate is based on the non-regulated sector's time course of the testing of oral fluid and urine in the past four years.

Cost and Benefit

Using data obtained from the Federal Workplace Drug Testing Programs and HHS certified laboratories, the Department estimates the number of specimens tested annually for federal agencies to be 150,000. HHS projects that approximately 7% (or 10,500) of the 150,000 specimens tested per year will be oral fluid specimens and 93% (or 139,500) will be urine specimens. The approximate annual numbers of regulated specimens for the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) are 6 million and 200,000, respectively. Should DOT and NRC allow oral fluid testing in regulated industries' workplace programs, the estimated annual numbers of specimens for DOT would be 180,000 oral fluid and 5,820,000 urine, and numbers of specimens for NRC would be 14,000 oral fluid and 186,000 urine.

In Section 3.4, the Department is proposing criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specifying the cross-reactivity of the immunoassay to the other analytes(s) within the group. These proposed Guidelines allow the use of methods other than immunoassay for initial testing. In addition, these proposed Guidelines include an alternative for laboratories to continue to use existing FDA-cleared immunoassays which do not have the specified cross-reactivity, by establishing a decision point with the lowest-reacting analyte. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

Costs associated with the addition of oral fluid testing and testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal based on information from some HHS certified laboratories currently testing non-regulated oral fluid specimens. Likewise, there will be minimal costs associated with changing initial testing to include MDA and MDEA

since current immunoassays can be adapted to test for these analytes. Prior to being allowed to test regulated oral fluid specimens, laboratories must be certified by the Department through the NLCP. Estimated laboratory costs to complete and submit the application are \$2,000, and estimated costs for the Department to process the application are \$7,200. These estimates are from SAMHSA are based on the NLCP fee schedule and historical costs. The initial certification process includes the requirement to demonstrate that their performance meets Guidelines requirements by testing three (3) groups of PT samples. The Department will provide the three groups of PT samples through the NLCP at no cost. Based on costs charged for urine specimen testing, laboratory costs to conduct the PT testing would range from \$900 to \$1,800 for each applicant laboratory.

Agencies choosing to use oral fluid in their drug testing programs may also incur some costs for training of federal employees such as drug program coordinators. Based on current training modules offered to drug program coordinators, and other associated costs including travel for 90% of drug program coordinators, the estimated total training cost for a one-day training session would be between \$54,000 and \$69,000. This training cost is included in the costs of the revised URMG.

Summary of One-Time Costs

	Lower		
	Bound	Upper Bound	Primary
Cost of Application*	-	-	\$62,000.00
Application	-	-	\$217,000.00

Processing*

Performance Testing*	\$27,900.00	\$55,800.00
Training*	\$54,000.00	\$69,000.00
Total	\$360,900.00	\$403,800.00

*Estimated using costs presented above multiplied by the number of laboratories (31).

Costs and Benefits

Thus, the Department estimates one-time, upfront costs of between \$360,000 and \$400,000. While the Department has only monetized a small portion of the benefits (time savings) to a small subset of the workplace drug testing programs that could be affected by the OFMG (i.e., Federal employee testing programs and not drug testing programs conducted under NRC and DOT regulations), the Department is confident that the benefits would outweigh the costs. Even if NRC and DOT do not implement oral fluid testing, the benefits to Federal workplace testing programs, estimated at between \$400,000 and \$1.2 million, would recur on annual basis.

Regulatory Flexibility Analysis

For the reasons outlined above, the Secretary has determined that the proposed Guidelines will not have a significant impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act [5 U.S.C. 605(b)]. The flexibility added by the

OFMG will not require addition expenditures. Therefore, an initial regulatory flexibility analysis is not required for this notice.

As mentioned in the section on Executive Orders 13563 and 12866, the Secretary anticipates that there will be an overall reduction in costs if drug testing is expanded under the OFMG. The costs to implement this change to regulation are negligible. The added flexibility will permit federal agencies to select the specimen type best suited for their needs and to authorize collection of an alternative specimen type when an employee is unable to provide the originally authorized specimen type. Insofar as there are costs associated with each drug test, this could lead to lower overall testing costs for federal agencies. The added flexibility will also benefit federal employees, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

The Secretary has determined that the proposed Guidelines are not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of \$100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This is not a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

Unfunded Mandates

The Secretary has examined the impact of the proposed Guidelines under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under section 202(a) of the UMRA because the proposed Guidelines do not impose a mandate that results in an expenditure of \$100 million (adjusted

annually for inflation) or more by either state, local, and tribal governments in the aggregate or by the private sector in any one year.

Environmental Impact

The Secretary has considered the environmental effects of the OFMG. No information or comments have been received that would affect the agency's determination there would be a significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

Executive Order 13132: Federalism

The Secretary has analyzed the proposed Guidelines in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt state law. As defined in the Order, "policies that have federalism implications" refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

In this notice, the Secretary is proposing to establish standards for certification of laboratories engaged in oral fluid drug testing for federal agencies and the use of oral fluid testing in federal drug-free workplace programs. The Department of Health and Human Services, by authority of Section 503 of Public Law 100-71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. Because the Mandatory Guidelines govern standards applicable to the

management of federal agency personnel, there should be little, if any, direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Secretary has determined that the Guidelines do not contain policies that have federalism implications.

Paperwork Reduction Act of 1995

The proposed Guidelines contain information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 [the PRA 44 U.S.C. 3507(d)]. Information collection and recordkeeping requirements which would be imposed on laboratories engaged in drug testing for federal agencies concern quality assurance and quality control documentation, reports, performance testing, and inspections as set out in subparts H, I, K, L, M and N. To facilitate ease of use and uniform reporting, a Federal CCF for each type of specimen collected will be developed as referenced in section 6.1. The Department has submitted the information collection and recordkeeping requirements contained in the proposed Guidelines to OMB for review and approval.

Privacy Act

The Secretary has determined that the Guidelines do not contain information collection requirements constituting a system of records under the Privacy Act. The Federal Register notice announcing the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid is not a system of records as noted in the information collection/recordkeeping requirements below. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the Federal Register on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004

[69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008 [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires SAMHSA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” as defined in the Executive Order, include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.” The proposed Guidelines do not have tribal implications. The Guidelines will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175.

Information Collection/Record Keeping Requirements

The information collection requirements (i.e., reporting and recordkeeping) in the current Guidelines, which establish the scientific and technical guidelines for federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for federal agencies under authority of 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget (OMB) under control number 0930-0158. The Federal Drug Testing Custody and Control Form used to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for

Medical Review Officers to make a determination, the National Laboratory Certification Program (NLCP) application, the NLCP Laboratory Information Checklist, and recordkeeping requirements in the current Guidelines, as approved under control number 0930-0158, will remain in effect until final Guidelines including the use of oral fluid specimens are issued.

The title, description and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting, disclosure and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens

Description: The Guidelines establish the scientific and technical guidelines for federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for federal agencies under authority of Public Law 100-71, 5 U.S.C. section 7301 note, and Executive Order No. 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions. The program has depended on urine specimen testing since 1988; the reporting, recordkeeping and disclosure requirements associated with urine specimen testing are approved under OMB control number 0930-0158. Since 1988, several products have appeared on the market making it easier for individuals to adulterate the urine specimen. Scientific advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in federal programs with the same level of confidence that has been applied to the use of urine. The proposed Guidelines establish when oral fluid specimens may be

collected, the procedures that must be used in collecting an oral fluid specimen, and the certification process for approving a laboratory to test oral fluid specimen.

Description of Respondents: Individuals or households; businesses; or other-for-profit; not-for-profit institutions.

The burden estimates in the tables below are based on the following number of respondents: 38,000 donors who apply for employment in testing designated positions, 100 collectors, 10 oral fluid specimen testing laboratories, and 100 MROs.

Estimate of Annual Reporting Burden

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
9.2(a)(1)	Laboratory required to submit application for certification	10	1	3	30
9.10(a)(3)	Materials to submit to become an HHS inspector	10	1	2	20
11.3(a)	Laboratory submits qualifications of RP to HHS	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP	10	1	2	20
11.20	Specifications for laboratory	10	5	0.5	25

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
	semi-annual statistical report of test results to each federal agency				
13.9 & 14.6	Specifies that MRO must report all verified split specimen test results to the federal agency	100	5	0.05 (3 min)	25
16.1(b) & 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period	1	1	0.5	0.5

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
16.7(a)	Specifies contents of appellant submission for review	1	1	50	50
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation	1	1	3	3
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
TOTAL		156			247

The following reporting requirements are also in the proposed Guidelines, but have not been addressed in the above reporting burden table: collector must report any unusual donor behavior or refuse to participate in the collection process on the Federal CCF (sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (section 10.3(a)); MRO notifies the federal agency and HHS when an error occurs on a blind sample (section 10.4(c)); section 13.5 describes the actions an MRO takes to report a primary specimen result; and section 14.5 describes the actions an MRO takes to report a split specimen result. SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the

burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to federal agencies.

Estimate of Annual Disclosure Burden

Section	Purpose	No. of Responde nts	Responses / Responde nt	Hours/ Response	Total Hours
8.3(a) & 8.6(b)(2)	Collector must contact federal agency point of contact	100	1	0.05 (3 min)	5
11.21 & 11.22	Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO	10	10	3	1,500
13.8 (b)	MRO must inform donor of right to request split specimen test when a positive or adulterated result is reported	100	5	3	1,500
TOTAL		210			3,505

The following disclosure requirements are also included in the proposed Guidelines, but have not been addressed in the above disclosure burden table: the collector must explain the

basic collection procedure to the donor and answer any questions (section 8.3(f) and (h), and must review the procedures for the oral fluid specimen collection device used with the donor (section 8.4(b)). SAMHSA believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

Estimate of Annual Recordkeeping Burden

Section	Purpose	No. of Responde nts	Responses / Responde nt	Hours/ Response	Total Hours
8.3, 8.5, & 8.8	Collector completes Federal CCF for specimen collected	100	380	0.07 (4 min)	2,534
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF	38,000	1	0.08 (5 min)	3,167
11.8(a) & 11.17	Laboratory completes Federal CCF upon receipt of specimen and before reporting result	10	3,800	0.05 (3 min)	1,900
13.4(d) (4), 13.9 (c), & 14.6(c)	MRO completes Federal CCF before reporting the result	100	380	0.05 (3 min)	1,900

Section	Purpose	No. of Responde nts	Responses / Responde nt	Hours/ Response	Total Hours
14.1(b)	MRO documents donor's request to have split specimen tested	300	1	0.05 (3 min)	15
TOTAL		38,510			9,516

The proposed Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector [section 4.3(a)(3)] and the documentation must be maintained in the collector's training file [section 4.3(c)]. SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a federal agency specimen, the collector is required to provide a statement [section 6.2(b)] explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H [sections 8.4(d) and 8.5(a)(1)] requires collectors to enter any information on the Federal CCF of any unusual findings during the oral fluid specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries are included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore,

not considered an additional recordkeeping burden. Subparts K describe a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records (i.e., sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.10(1); 11.13(a); 11.16; 11.17(a), (b), and (c); 11.20; 11.21, and 11.22. These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis.

Thus the total annual response burden associated with the testing of oral fluid specimens by the laboratories is estimated to be 13,268 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,809 hours currently approved by OMB under control number 0930-0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary has submitted a copy of these proposed Guidelines to OMB for its review. Comments on the information collection requirements are specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

OMB is required to make a decision concerning the collection of information contained in these proposed Guidelines between 30 and 60 days after publication of this document in the

Federal Register. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to HHS on the proposed Guidelines.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street, NW, Washington, DC 20502, Attn: Desk Officer for SAMHSA. Because of delays in receipt of mail, comments may also be sent to (202) 395-6974 (fax).

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The Department believes that the benefits of the proposed Mandatory Guidelines using Oral Fluid Specimens outweigh the costs to include this additional specimen type in federal workplace drug testing programs. There is no requirement for federal agencies to use oral fluid as part of their drug testing program. A federal agency may choose to use urine, oral fluid, or both specimen types in their program based on the agency's mission, its employees' duties, and

the danger to the public health and safety or to national security that could result from an employee's failure to carry out the duties of his or her position.

Pamela S. Hyde,
Administrator, SAMHSA.

May 4, 2015

Date

Sylvia M. Burwell,
Secretary.

May 7, 2015_

Date

For reasons set forth in the preamble, the Department proposes to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to include Mandatory Guidelines using Oral Fluid Specimens to read as follows:

MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS USING ORAL FLUID SPECIMENS

Subpart A – Applicability

- 1.1 To whom do these Guidelines apply?
- 1.2 Who is responsible for developing and implementing these Guidelines?
- 1.3 How does a federal agency request a change from these Guidelines?
- 1.4 How are these Guidelines revised?
- 1.5 What do the terms used in these Guidelines mean?
- 1.6 What is an agency required to do to protect employee records?
- 1.7 What is a refusal to take a federally regulated drug test?
- 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

Subpart B – Oral Fluid Specimens

- 2.1 What type of specimen may be collected?
- 2.2 Under what circumstances may an oral fluid specimen be collected?
- 2.3 How is each oral fluid specimen collected?
- 2.4 What volume of oral fluid is collected?
- 2.5 How is the split oral fluid specimen collected?
- 2.6 When may an entity or individual release an oral fluid specimen?

Subpart C – Oral Fluid Specimen Tests

- 3.1 Which tests are conducted on an oral fluid specimen?
- 3.2 May a specimen be tested for additional drugs?
- 3.3 May any of the specimens be used for other purposes?
- 3.4 What are the drug test cutoff concentrations for undiluted (neat) oral fluid?
- 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?
- 3.6 What criteria are used to report an oral fluid specimen as adulterated?
- 3.7 What criteria are used to report an invalid result for an oral fluid specimen?

Subpart D - Collectors

- 4.1 Who may collect a specimen?
- 4.2 Who may not collect a specimen?
- 4.3 What are the requirements to be a collector?
- 4.4 What are the requirements to be a trainer for collectors?
- 4.5 What must a federal agency do before a collector is permitted to collect a specimen?

Subpart E - Collection Sites

- 5.1 Where can a collection for a drug test take place?
- 5.2 What are the requirements for a collection site?
- 5.3 Where must collection site records be stored?
- 5.4 How long must collection site records be stored?

- 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?
- 5.6 What are the privacy requirements when collecting an oral fluid specimen?

Subpart F - Federal Drug Testing Custody and Control Form

- 6.1 What federal form is used to document custody and control?
- 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

Subpart G – Oral Fluid Specimen Collection Devices

- 7.1 What is used to collect an oral fluid specimen?
- 7.2 What are the requirements for an oral fluid collection device?
- 7.3 What are the minimum performance requirements for a collection device?

Subpart H – Oral Fluid Specimen Collection Procedure

- 8.1 What privacy must the donor be given when providing an oral fluid specimen?
- 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?
- 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?
- 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?
- 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?
- 8.6 What procedure is used when the donor states that he or she is unable to provide an oral

fluid specimen?

- 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?
- 8.8 How does the collector prepare the oral fluid specimens?
- 8.9 How does the collector report a donor's refusal to test?
- 8.10 What are a federal agency's responsibilities for a collection site?

Subpart I - HHS Certification of Laboratories

- 9.1 Who has the authority to certify laboratories to test oral fluid specimens for federal agencies?
- 9.2 What is the process for a laboratory to become HHS-certified?
- 9.3 What is the process for a laboratory to maintain HHS certification?
- 9.4 What is the process when a laboratory does not maintain its HHS certification?
- 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?
- 9.6 What are the PT requirements for an applicant laboratory?
- 9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?
- 9.8 What are the inspection requirements for an applicant laboratory?
- 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?
- 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?
- 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

- 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?
- 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?
- 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?
- 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?
- 9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?
- 9.17 Where is the list of HHS-certified laboratories published?

Subpart J - Blind Samples Submitted by an Agency

- 10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?
- 10.2 What are the requirements for blind samples?
- 10.3 How is a blind sample submitted to an HHS-certified laboratory?
- 10.4 What happens if an inconsistent result is reported for a blind sample?

Subpart K - Laboratory

- 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?
- 11.2 What are the responsibilities of the responsible person (RP)?

- 11.3 What scientific qualifications must the RP have?
- 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?
- 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?
- 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?
- 11.7 What security measures must an HHS-certified laboratory maintain?
- 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?
- 11.9 What are the requirements for an initial drug test?
- 11.10 What must an HHS-certified laboratory do to validate an initial drug test?
- 11.11 What are the batch quality control requirements when conducting an initial drug test?
- 11.12 What are the requirements for a confirmatory drug test?
- 11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?
- 11.14 What are the batch quality control requirements when conducting a confirmatory drug test?
- 11.15 What are the analytical and quality control requirements for conducting specimen validity tests?
- 11.16 What must an HHS-certified laboratory do to validate a specimen validity test?
- 11.17 What are the requirements for an HHS-certified laboratory to report a test result?
- 11.18 How long must an HHS-certified laboratory retain specimens?
- 11.19 How long must an HHS-certified laboratory retain records?
- 11.20 What statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?

- 11.21 What HHS-certified laboratory information is available to a federal agency?
- 11.22 What HHS-certified laboratory information is available to a federal employee?
- 11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

Subpart L - Instrumented Initial Test Facility (IITF)

- 12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?

Subpart M - Medical Review Officer (MRO)

- 13.1 Who may serve as an MRO?
- 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?
- 13.3 What training is required before a physician may serve as an MRO?
- 13.4 What are the responsibilities of an MRO?
- 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?
- 13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?
- 13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?
- 13.8 Who may request a test of a split (B) specimen?
- 13.9 How does an MRO report a primary (A) specimen test result to an agency?
- 13.10 What types of relationships are prohibited between an MRO and an HHS-certified

laboratory?

Subpart N - Split Specimen Tests

- 14.1 When may a split (B) specimen be tested?
- 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?
- 14.3 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported adulterated?
- 14.4 Who receives the split (B) specimen result?
- 14.5 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?
- 14.6 How does an MRO report a split (B) specimen test result to an agency?
- 14.7 How long must an HHS-certified laboratory retain a split (B) specimen?

Subpart O - Criteria for Rejecting a Specimen for Testing

- 15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?
- 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?
- 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?
- 15.4 What discrepancies may require an MRO to cancel a test?

Subpart P - Laboratory Suspension/Revocation Procedures

- 16.1 When may the HHS certification of a laboratory be suspended?
- 16.2 What definitions are used for this subpart?
- 16.3 Are there any limitations on issues subject to review?
- 16.4 Who represents the parties?
- 16.5 When must a request for informal review be submitted?
- 16.6 What is an abeyance agreement?
- 16.7 What procedures are used to prepare the review file and written argument?
- 16.8 When is there an opportunity for oral presentation?
- 16.9 Are there expedited procedures for review of immediate suspension?
- 16.10 Are any types of communications prohibited?
- 16.11 How are communications transmitted by the reviewing official?
- 16.12 What are the authority and responsibilities of the reviewing official?
- 16.13 What administrative records are maintained?
- 16.14 What are the requirements for a written decision?
- 16.15 Is there a review of the final administrative action?

Subpart A - Applicability

Section 1.1 To whom do these Guidelines apply?

- (a) These Guidelines apply to:
 - (1) Executive Agencies as defined in 5 U.S.C. 105;
 - (2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed

Forces as defined in 5 U.S.C. 2101(2));

(3) Any other employing unit or authority of the federal government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories that provide drug testing services to the federal agencies;

(6) Collectors who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.¹

Section 1.2 Who is responsible for developing and implementing these Guidelines?

(a) Executive Order 12564 and Public Law 100-71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for federal workplace

¹ The NRC-related information in this notice pertains to individuals subject to drug testing conducted pursuant to 10 CFR Part 26, "Fitness for Duty Programs" (i.e., employees of certain NRC-regulated entities).

¹ Although HHS has no authority to regulate the transportation industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that "incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988 and any amendments to those guidelines..." See, e.g., 49 U.S.C. §20140(c)(2). In carrying out its mandate, DOT requires by regulation at 49 CFR Part 40 that its federally-regulated employers use only HHS-certified laboratories in the testing of employees, 49 CFR §40.81, and incorporates the scientific and technical aspects of the HHS Mandatory Guidelines.

drug testing programs.

- (b) The Secretary has the responsibility to implement these Guidelines.

Section 1.3 How does a federal agency request a change from these Guidelines?

(a) Each federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

Section 1.4 How are these Guidelines revised?

(a) To ensure the full reliability and accuracy of specimen tests, the accurate reporting of test results, and the integrity and efficacy of federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

- (b) The changes will be published in final as a notice in the **Federal Register**.

Section 1.5 What do the terms used in these Guidelines mean?

The following definitions are adopted:

Accessioner. The individual who signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

Adulterated Specimen. A specimen that has been altered, as evidenced by test results

showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

Aliquot. A portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (e.g., drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Device. A product that is used to collect an oral fluid specimen and may include a buffer or diluent.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

Confirmatory Drug Test. A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support a specimen validity test result.

Control. A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Cutoff. The analytical value (e.g., drug or drug metabolite concentration) used as the decision point to determine a result (e.g., negative, positive, adulterated, invalid, or, for urine,

substituted) or the need for further testing.

Donor. The individual from whom a specimen is collected.

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB) approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (i.e., HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is invalid, adulterated, or (for urine) diluted or substituted.

Instrumented Initial Test Facility (IITF). A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

Invalid Result. The result reported by an HHS-certified laboratory when the laboratory determines that it cannot complete testing or obtain a valid drug test result.

Laboratory. A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection. The lowest concentration at which the analyte (e.g., drug or drug

metabolite) can be identified.

Limit of Quantification. For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (e.g., drug or drug metabolite) can be accurately established.

Lot. A number of units of an item (e.g., reagents, quality control material, oral fluid collection device) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the federal agency.

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Non-Medical Use of a Drug. The use of a prescription drug, whether obtained by prescription or otherwise, other than in the manner or for the time period prescribed, or by a person for whom the drug was not prescribed.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

Positive Result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmation cutoff concentration.

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2)

Responsible Person (RP). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified laboratory.

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. A sample collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Oral Fluid). A collection in which two specimens [primary (A) and split (B)] are collected, concurrently or serially, and independently sealed in the presence of the donor.

Standard. Reference material of known purity or a solution containing a reference material at a known concentration.

Section 1.6 What is an agency required to do to protect employee records?

Consistent with 5 U.S.C. 552a and 48 CFR 24.101-24.104, all agency contracts with

laboratories, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100-71. Each federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

In addition, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR Parts 160 and 164, Subparts A and E, is applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit <http://www.hhs.gov/ocr/hipaa>.

Section 1.7 What is a refusal to take a federally regulated drug test?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete (with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test);

(3) Fail to provide a specimen (e.g., oral fluid or another authorized specimen type) for any drug test required by these Guidelines or federal agency regulations (with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test);

(4) Fail or decline to participate in an alternate specimen collection (e.g., urine) as directed by the federal agency or collector (i.e., as described in Section 8.6);

(5) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (i.e., Section 13.6) or as directed by the federal agency. In the case of a federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(6) Fail to cooperate with any part of the testing process (e.g., disrupt the collection process); or

(7) Admit to the collector or MRO that you have adulterated or (for urine) substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) As a federal agency employee or applicant, a refusal to take a test may result in the initiation of disciplinary or adverse action, up to and including removal from, or non-selection for, federal employment.

(b) When a donor has refused to participate in a part of the collection process, the collector must terminate that portion of the collection process and take action as described in Section 8.9: immediately notify the federal agency's designated representative by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received, document the refusal on the Federal CCF, sign and date the Federal CCF, and send all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

- (1) Checking the refusal to test box;
- (2) Providing a reason for the refusal in the remarks line; and
- (3) Signing and dating the MRO copy of the Federal CCF.

Subpart B - Oral Fluid Specimens

Section 2.1 What type of specimen may be collected?

A federal agency may collect oral fluid and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using oral fluid must follow these Guidelines.

Section 2.2 Under what circumstances may an oral fluid specimen be collected?

A federal agency may collect an oral fluid specimen for the following reasons:

- (a) Federal agency applicant/Pre-employment test;
- (b) Random test;
- (c) Reasonable suspicion/cause test;
- (d) Post-accident test;
- (e) Return to duty test; or
- (f) Follow-up test.

Section 2.3 How is each oral fluid specimen collected?

Each oral fluid specimen is collected as a split specimen (i.e., collected either simultaneously or serially) as described in Section 2.5.

Section 2.4 What volume of oral fluid is collected?

A known volume of at least 1 mL of undiluted (neat) oral fluid for each oral fluid specimen (designated “Tube A” and “Tube B”) is collected using a collection device.

Section 2.5 How is the split oral fluid specimen collected?

The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as “A” (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as “B” (split) either simultaneously or serially (i.e., as described in Section 8.8.)

Section 2.6 When may an entity or individual release an oral fluid specimen?

Entities and individuals subject to these Guidelines under Section 1.1, may not release specimens collected pursuant to Executive Order 12564, Public Law 100-71 and these Guidelines, to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.8.

Subpart C – Oral Fluid Drug and Specimen Validity Tests

Section 3.1 Which tests are conducted on an oral fluid specimen?

A federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine as provided under Section 3.4;

(b) Is authorized to test each specimen for opiates, amphetamines, and phencyclidine, as provided under Section 3.4; and

(c) Must ensure that the following specimen validity tests are conducted on each oral fluid specimen:

(1) Determine the albumin concentration on every specimen; or

(2) Determine the immunoglobulin G (IgG) concentration on every specimen.

(d) If a specimen exhibits abnormal characteristics (e.g., unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (e.g., non-recovery of internal standard, unusual response), or contains an unidentified substance

that interferes with the confirmatory analysis, then additional testing may be performed.

Section 3.2 May a specimen be tested for additional drugs?

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a federal agency employee may be tested by the federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act (other than the drugs listed in Section 3.1, or when used pursuant to a valid prescription or when used as otherwise authorized by law). The federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in Section 3.1. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

Section 3.3 May any of the specimens be used for other purposes?

(a) Specimens collected pursuant to Executive Order 12564, Public Law 100-71, and these Guidelines must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees or any other entity, for other purposes (e.g., deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies, specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

Section 3.4 What are the drug test cutoff concentrations for undiluted (neat) oral fluid?

Initial Test Analyte	Initial Test Cutoff	Confirmatory Test Analyte	Confirmatory Test Cutoff Concentration
Marijuana (THC) ¹	4 ng/mL	THC	2 ng/mL
Cocaine / Benzoyllecgonine	15 ng/mL ²	Cocaine Benzoyllecgonine	8 ng/mL 8 ng/mL
Codeine/ Morphine	30 ng/mL ²	Codeine Morphine	15 ng/mL 15 ng/mL
Hydrocodone/ Hydromorphone	30 ng/mL ²	Hydrocodone Hydromorphone	15 ng/mL 15 ng/mL
Oxycodone/ Oxymorphone	30 ng/mL ²	Oxycodone Oxymorphone	15 ng/mL 15 ng/mL

6-Acetylmorphine	3 ng/mL	6-Acetylmorphine	2 ng/mL
Phencyclidine	3 ng/mL	Phencyclidine	2 ng/mL
Amphetamine/ Methamphetamine	25 ng/mL ²	Amphetamine Methamphetamine	15 ng/mL 15 ng/mL
MDMA ⁴ /MDA ⁵ / MDEA ⁶	25 ng/mL ²	MDMA ³ MDA ⁴ MDEA ⁵	15 ng/mL 15 ng/mL 15 ng/mL
¹ Δ-9-Tetrahydrocannabinol (THC)			
<p>²<u>Immunoassay:</u> The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.</p> <p><u>Alternate technology:</u> Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.</p>			
³ Methylenedioxymethamphetamine (MDMA)			
⁴ Methylenedioxyamphetamine (MDA)			
⁵ Methylenedioxyethylamphetamine (MDEA)			

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests as necessary to provide information that the MRO would use to report a verified drug test result [e.g., d, l-stereoisomers determination for methamphetamine, Δ -9-tetrahydrocannabinol-9-carboxylic acid (THCA), and additional specimen validity tests including adulterants]. All tests must meet appropriate validation and quality control requirements.

Section 3.6 What criteria are used to report an oral fluid specimen as adulterated?

An HHS-certified laboratory reports an oral fluid specimen as adulterated when the presence of an adulterant is verified using an initial test on a first aliquot and a different confirmatory test on a second aliquot.

Section 3.7 What criteria are used to report an invalid result for an oral fluid specimen?

An HHS-certified laboratory reports a primary (A) oral fluid specimen as an invalid result when:

(a) The albumin concentration is less than 0.6 mg/dL for both the initial (first) test and the second test on two separate aliquots;

(b) The IgG concentration is less than 0.5 mg/L for both the initial (first) test and the second test on two separate aliquots;

(c) Interference occurs on the initial drug tests on two separate aliquots (i.e., valid immunoassay or alternate technology initial drug test results cannot be obtained);

(d) Interference with the drug confirmatory assay occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(e) The physical appearance of the specimen (e.g., viscosity) is such that testing the specimen may damage the laboratory's instruments;

(f) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (e.g., color) are clearly different; or

(g) The concentration of a biomarker other than albumin or IgG is not consistent with that established for human oral fluid.

Subpart D - Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work together with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect his or her own drug testing specimen.

(c) An employee working for an HHS-certified laboratory must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (e.g., spouse, ex-spouse, relative) or a close personal friend (e.g., fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if he or she fulfills the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to these Guidelines;

(3) Is trained and qualified to use the specific oral fluid collection device. Training must include the following:

(i) All steps necessary to complete an oral fluid collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process,

ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include two uneventful collection scenarios, one insufficient specimen quantity scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen collection device tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are “error-free.”

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of his or her training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until his or her training as a collector has been properly documented.

Section 4.4 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors for a specific oral fluid collection device and may train others to collect oral fluid specimens using that collection device when they have completed the following:

(1) Qualified as a trained collector and regularly conducted oral fluid drug test collections using that collection device for a period of at least one year or

(2) Completed a “train the trainer” course given by an organization (e.g., manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of his or her training and provide that documentation to a federal agency when requested.

Section 4.5 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (e.g., third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

Subpart E - Collection Sites

Section 5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work

site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (e.g., an accident investigation), another site may be used for the collection, providing the collection is performed by a trained oral fluid specimen collector.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

- (a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);
- (b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;
- (c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory;
- (d) A restricted access area where only authorized personnel may be present during the collection;
- (e) A restricted access area for the storage of collection supplies; and
- (f) The ability to store records securely.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (e.g., collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during, and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering.

(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory.

Section 5.6 What are the privacy requirements when collecting an oral fluid specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F - Federal Drug Testing Custody and Control Form

Section 6.1 What federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used for an oral fluid specimen?

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector uses an incorrect form, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory or MRO discovers that an incorrect form was used by the collector, the laboratory or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record

cannot be obtained, the HHS-certified laboratory must wait at least 5 business days before the laboratory reports a rejected for testing result to the MRO and the MRO cancels the test.

Subpart G – Oral Fluid Specimen Collection Devices

Section 7.1 What is used to collect an oral fluid specimen?

An FDA-cleared single-use collection device intended to collect an oral fluid specimen must be used. This collection device must maintain the integrity of such specimens during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites.

Section 7.2 What are the requirements for an oral fluid collection device?

An oral fluid specimen collection device must provide:

- (a) An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected;
- (b) A sealable, non-leaking container that maintains the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites;
- (c) Components that ensure pre-analytical drug and drug metabolite stability; and
- (d) Components that do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen.

Section 7.3 What are the minimum performance requirements for a collection device?

An oral fluid collection device must meet the following minimum performance requirements.

(a) Reliable and reproducible collection of a minimum of 1 mL of undiluted (neat) oral fluid;

(b) If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):

(1) The volume of oral fluid collected should be within 0.1 ml of the target volume, and

(2) The volume of diluent in the device should be within 0.05 ml of the diluent target volume;

(c) Stability (recoverable concentrations ≥ 90 percent of the concentration at the time of collection) of the drugs and/or drug metabolites for one week at room temperature (18-25 °C) and under intended shipping and storage conditions; and

(d) Recover ≥ 90 percent (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff (see Section 3.4).

Subpart H – Oral Fluid Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing an oral fluid specimen?

The following privacy requirements apply when a donor is providing an oral fluid specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor.

Section 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

The collector must deter the adulteration or substitution of an oral fluid specimen at the collection site.

Section 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

The collector must take the following steps before beginning an oral fluid specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (e.g., driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector requests that the donor opens his or her mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (e.g., candy, gum, food, tobacco, dental retainer).

(1) At this time, the collector starts the 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in Section 8.5.

(2) If the donor's mouth is not free of any items that could impede or interfere with the collection of an oral fluid specimen immediately prior to collection, or the donor claims to be a tobacco user, or claims to have "dry mouth," the donor may drink while rinsing his or her mouth with water (up to 4 oz.) and wait 10 minutes before beginning the specimen collection.

(e) The collector must provide identification (e.g., employee badge, employee list) if requested by the donor.

(f) The collector explains the basic collection procedure to the donor.

(g) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or available upon request.

(h) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

(a) The collector will provide or the donor may select a specimen collection device that is clean, unused, and wrapped/sealed in original packaging. The specimen collection device will be opened in view of the donor.

(1) Both the donor and the collector must keep the unwrapped collection devices in view at all times until each collection device containing the donor's oral fluid specimen has been sealed and labeled.

(b) The collector reviews with the donor the procedures required for a successful oral

fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(1) The collector may set a reasonable time limit for specimen collection (based on the device used, not to exceed 15 minutes per device)

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen, the collector must note the conduct on the Federal CCF.

Section 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the oral fluid specimen:

(a) The collector shall be present and maintain visual contact with the donor during the procedures outlined in this section.

(1) Under the observation of the collector, the donor is responsible for placing the specimen collection device in his or her mouth. The collector must ensure the collection is performed correctly and that the collection device is working properly. If the device fails to collect the specimen, the collector must begin the process again, beginning with Step 8.4(b), using a new specimen collection device (for both A and B specimens) and a new Federal CCF.

(2) The donor and collector must complete the collection in accordance with the manufacturer instructions for the collection device.

(b) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection device, refuses to provide a second specimen as

required in step (a)(1) above, or refuses to provide an alternate specimen as authorized in Section 8.6, the collector stops the collection and reports the refusal to test in accordance with Section 8.9.

Section 8.6 What procedure is used when the donor states that he or she is unable to provide an oral fluid specimen?

(a) If the donor states that he or she is unable to provide an oral fluid specimen during the collection process, the collector requests that the donor follow the collector instructions and attempt to provide an oral fluid specimen.

(b) The donor demonstrates his or her inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

(1) If the donor states that he or she could provide a specimen after drinking some fluids, the collector gives the donor a drink (up to 8 ounces) and waits an additional 10 minutes before beginning the specimen collection (a period of 1 hour must be provided or until the donor has provided a sufficient oral fluid specimen). If the donor simply needs more time before attempting to provide an oral fluid specimen, the donor is not required to drink any fluids during the 1 hour wait time. The collector must inform the donor that the donor must remain at the collection site (i.e., in an area designated by the collector) during the wait period.

(2) If the donor states that he or she is unable to provide an oral fluid specimen, the collector records the reason for not collecting an oral fluid specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal

agency's designated representative. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

Section 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

No, unless the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

Section 8.8 How does the collector prepare the oral fluid specimens?

- (a) All federal agency collections are to be split specimen collections.

An oral fluid split specimen collection may be:

- (1) Two specimens collected simultaneously with two separate collection devices;
- (2) Two specimens collected serially with two separate collection devices. Collection of the second specimen must begin within two minutes after the completion of the first collection and recorded on the Federal CCF; or

- (3) Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes.

- (b) A known volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as "Tube A" and a known volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as "Tube B".

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over the cap of each specimen tube. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen tube. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all the information required on the Federal CCF is provided.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from him or her. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints his or her name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Tube A and Tube B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory that will be testing the Tube A oral fluid specimen. The collector must also send a copy of the Federal CCF to the HHS-certified laboratory.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

Section 8.9 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any oral fluid specimen collected and reports the refusal to test by:

- (a) Notifying the federal agency by means (e.g., telephone, e-mail, or secure fax) that ensures that the notification is immediately received,
- (b) Documenting the refusal to test on the Federal CCF, and
- (c) Sending all copies of the Federal CCF to the federal agency's designated representative.

Section 8.10 What are a federal agency's responsibilities for a collection site?

- (a) A federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H.
- (b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (e.g., virtual, onsite, or self-evaluation).
- (c) A federal agency must investigate reported collection site deficiencies (e.g., specimens reported "rejected for testing" by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (i.e., using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I - HHS Certification of Laboratories

Section 9.1 Who has the authority to certify laboratories to test oral fluid specimens for federal agencies?

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any HHS-certified laboratory, including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory to send specimens or specimen aliquots to another HHS-certified laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory is prohibited from stating or implying that it is certified by HHS under these Guidelines to test oral fluid specimens for federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory to become HHS-certified?

(a) A laboratory seeking HHS certification must:

(1) Submit a completed OMB-approved application form (i.e., the applicant laboratory provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

(2) Have its application reviewed as complete and accepted by HHS;

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

Section 9.3 What is the process for a laboratory to maintain HHS certification?

(a) To maintain HHS certification, a laboratory must:

(1) Successfully participate in both the maintenance PT and inspection programs (i.e., successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory does not maintain its HHS certification?

- (a) A laboratory that does not maintain its HHS certification must:
- (1) Stop testing federally regulated specimens;
 - (2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.18, 11.19, and 14.7;
 - (3) Ensure access to federally regulated specimens and records in accordance with Sections 11.21 and 11.22 and Subpart P; and
 - (4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in Subpart P that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

- (a) PT samples used to evaluate drug tests will be prepared using the following specifications:
- (1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in Section 3.4 and may be sent to the laboratory as undiluted (neat) oral fluid. The PT samples must satisfy one of the following parameters:
 - (i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff concentration for the drug or drug metabolite;
 - (ii) The concentration of a drug or metabolite may be less than 40 percent of the confirmatory test cutoff concentration when the PT sample is designated as a retest sample; or
 - (iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance or other substances for special purposes.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) PT samples used to evaluate specimen validity tests shall satisfy, but are not limited to the following criteria:

(1) The concentration of albumin and/or IgG will be at least 20 percent below the cutoff;

or

(2) The concentration of albumin and/or IgG may be another concentration for a special purpose.

(c) The laboratory must (to the greatest extent possible) handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

Section 9.6 What are the PT requirements for an applicant laboratory?

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations [i.e., no more than ± 20 percent or ± 2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 80 percent of the total drug challenges over the three sets of PT

samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by more than ± 50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations [i.e., no more than ± 20 percent or ± 2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the following criteria:

(i) Albumin concentrations are no more than ± 20 percent or ± 2 standard deviations from the appropriate reference or peer group mean; and

(ii) IgG values are no more than ± 20 percent or ± 2 standard deviations from the appropriate reference or peer group mean;

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

- (1) Have no false positive results;
- (2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;
- (3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;
- (4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ± 20 percent or ± 2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;
- (5) For the confirmatory drug tests, obtain no more than one drug concentration on a PT sample that differs by more than ± 50 percent from the appropriate reference or peer group mean over two consecutive PT cycles;
- (6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ± 20 percent or ± 2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;
- (7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;
- (8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;
- (9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the following criteria:
 - (i) Albumin concentrations are no more than ± 20 percent or ± 2 standard deviations from

the appropriate reference or peer group mean; and

(ii) IgG values are no more than ± 20 percent or ± 2 standard deviations from the appropriate reference or peer group mean.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the inspection requirements for an applicant laboratory?

(a) An applicant laboratory is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's testing procedures and facilities using an inspection checklist.

Section 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?

(a) An HHS-certified laboratory must undergo an inspection 3 months after becoming certified and at least every 6 months thereafter.

(b) An HHS-certified laboratory is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory must continue to satisfy the minimum requirements as stated in these Guidelines.

Section 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if he or she satisfies the following criteria:

(1) Has experience and an educational background similar to that required for either an HHS-certified laboratory responsible person or certifying scientist as described in Subpart K;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory.

(b) The Secretary or a federal agency may conduct an inspection at any time.

Section 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

If an applicant laboratory fails to satisfy the requirements established for the initial certification process, the laboratory must start the certification process from the beginning.

Section 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

(a) If an HHS-certified laboratory fails to satisfy the minimum requirements for certification, the laboratory is given a period of time (e.g., 5 or 30 working days depending on the nature of the deficiency) to provide any explanation for its performance and evidence that all

deficiencies have been corrected.

(b) A laboratory's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(d) If an HHS-certified laboratory's certification is revoked or suspended in accordance with the process described in Subpart P, the laboratory is not permitted to test federally regulated specimens until the suspension is lifted or the laboratory has successfully completed the certification requirements as a new applicant laboratory.

Section 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests (e.g., an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition

imposed on the HHS-certified laboratory by a federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory to ensure fully reliable and accurate drug test results and reports.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing.

Section 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?

(a) When a laboratory's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory with written notice of the suspension or proposed revocation by facsimile, mail, personal service, or

registered or certified mail, return receipt requested. This notice shall state the following:

- (1) The reasons for the suspension or proposed revocation;
- (2) The terms of the suspension or proposed revocation; and
- (3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notice, or if expedited review is requested, within 3 days of the date the laboratory received the notice. Subpart P contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified laboratory that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of Subpart P.

Section 9.16 May a laboratory that had its HHS certification revoked be recertified to test

federal agency specimens?

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.15 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory which has had its certification revoked may reapply for HHS certification as an applicant laboratory.

Section 9.17 Where is the list of HHS-certified laboratories published?

(a) The list of HHS-certified laboratories is published monthly in the **Federal Register**. This notice is also available on the Internet at <http://www.samhsa.gov/workplace>.

(b) An applicant laboratory is not included on the list.

Subpart J - Blind Samples Submitted by an Agency

Section 10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?

(a) Each federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency

must be negative and 25 percent must be positive for one or more drugs.

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier in the selected manufacturer's collection device as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in Section 3.4.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff concentration.

(b) Drug negative blind samples (i.e., certified to contain no drugs) must be validated by the supplier in the selected manufacturer's collection device as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory or IITF, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory?

(a) A blind sample must be submitted in the collection device with the current Federal CCF that the HHS-certified laboratory uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a

blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory reports a result for a blind sample that is inconsistent with the expected result (e.g., a laboratory reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory and attempt to determine if the laboratory made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K - Laboratory

Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

- (1) Chain of custody procedures;
- (2) Accessioning;
- (3) Security;
- (4) Quality control/quality assurance programs;
- (5) Analytical methods and procedures;
- (6) Equipment and maintenance programs;
- (7) Personnel training;
- (8) Reporting procedures; and
- (9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (e.g., publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days

or less (e.g., temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: the candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as

required prior to conducting federally regulated testing under a new RP.

Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (e.g., technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (i.e., receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before he or she is permitted to work independently with federally regulated specimens. All training must be documented.

Section 11.7 What security measures must an HHS-certified laboratory maintain?

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (i.e., for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (e.g., firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic

procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (e.g., spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.11.

Section 11.10 What must an HHS-certified laboratory do to validate an initial drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

- (2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;
 - (3) The effective concentration range of the test (linearity);
 - (4) The potential for carryover;
 - (5) The potential for interfering substances; and
 - (6) The potential matrix effects if using an alternate technology.
- (b) Each new lot of reagent must be verified prior to being placed into service.
 - (c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.11 What are the batch quality control requirements when conducting an initial drug test?

- (a) Each batch of specimens must contain the following controls:
 - (1) At least one control certified to contain no drug or drug metabolite;
 - (2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;
 - (3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and
 - (4) At least one control that appears as a donor specimen to the analysts.
- (b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.12 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification [e.g., gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS] or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of an oral fluid specimen when identifying and quantifying drugs or their metabolites.

Section 11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

- (1) The linear range of the analysis;
- (2) The limit of detection;
- (3) The limit of quantification;
- (4) The accuracy and precision at the cutoff concentration;
- (5) The accuracy (bias) and precision at 40 percent of the cutoff concentration;
- (6) The potential for interfering substances;
- (7) The potential for carryover; and
- (8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

- (1) A calibrator at the cutoff concentration;
- (2) At least one control certified to contain no drug or drug metabolite;
- (3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each specimen validity test result must be based on performing an initial specimen validity test on one aliquot and a second or confirmatory test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results; and

(c) Controls must be analyzed concurrently with specimens.

Section 11.16 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.17 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (e)(1) through (e)(4) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

(d) For a specimen that has an invalid result for one of the reasons stated in items (e)(1) through (e)(4) below, the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(e) A primary (A) oral fluid specimen is reported as an invalid result when:

(1) Interference occurs on the initial drug tests on two separate aliquots (i.e., valid initial

drug test results cannot be obtained);

(2) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

(3) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments;

(4) The physical appearances of Tubes A and B are clearly different (note: A is tested);

(5) The albumin concentration is less than 0.6 mg/dL for both the initial (first) test and the second test on two separate aliquots;

(6) The IgG concentration is less than 0.5 mg/L for both the initial (first) test and the second test on two separate aliquots; or

(7) The concentration of a biomarker other than albumin or IgG is not consistent with that established for human oral fluid.

(f) An HHS-certified laboratory shall reject a primary (A) oral fluid specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(g) An HHS-certified laboratory must report all positive, adulterated, and invalid test results for an oral fluid specimen. For example, a specimen can be positive for a specific drug and adulterated.

(h) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(i) An HHS-certified laboratory must report numerical values of the specimen validity

test results that support a specimen that is reported adulterated or invalid (as appropriate).

(j) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than “insert the actual value for the upper limit of the linear range,” or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method’s linear range and multiplying the result by the appropriate dilution factor.

(k) HHS-certified laboratories may transmit test results to the MRO by various electronic means (e.g., teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(l) HHS-certified laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(m) For positive, adulterated, invalid, and rejected specimens, laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.18 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, or as an invalid result for a minimum of 1 year.

(b) Retained specimens must be kept in secured frozen storage (-20 °C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period.

Section 11.19 How long must an HHS-certified laboratory retain records?

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.21) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.20 What statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail,

facsimile, or e-mail within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

- (1) Reporting period (inclusive dates);
- (2) HHS-certified laboratory name and address;
- (3) Federal agency name;
- (4) Number of specimen results reported;
- (5) Number of specimens collected by reason for test;
- (6) Number of specimens reported negative;
- (7) Number of specimens rejected for testing because of a fatal flaw;
- (8) Number of specimens rejected for testing because of an uncorrected flaw;
- (9) Number of specimens tested positive by each initial drug test;
- (10) Number of specimens reported positive;
- (11) Number of specimens reported positive for each drug and drug metabolite;
- (12) Number of specimens reported adulterated; and
- (13) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.

(c) An HHS- certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.21 What HHS-certified laboratory information is available to a federal agency?

(a) Following a federal agency's receipt of a positive or adulterated drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and

controls and copies of all internal chain of custody documents related to the confirmatory tests;
and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.22 What HHS-certified laboratory information is available to a federal employee?

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and the federal agency requesting copies of any records relating to his or her drug test results or a documentation package as described in Section 11.21(b) and any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100-71, and these Guidelines.

Section 11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a

potential conflict of interest.

Subpart L – Instrumented Initial Test Facility (IITF)

Section 12.1 May an IITF test oral fluid specimens for a federal agency’s workplace drug testing program?

No, only HHS-certified laboratories are authorized to test oral fluid specimens for federal agency workplace drug testing programs in accordance with these Guidelines.

Subpart M - Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

- (a) A currently licensed physician who has:
 - (1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;
 - (2) Knowledge regarding the pharmacology and toxicology of illicit drugs and nonmedical use of prescription drugs;
 - (3) The training necessary to serve as an MRO as set out in Section 13.3;
 - (4) Satisfactorily passed an initial examination administered by a nationally recognized entity or subspecialty board that has been approved by the Secretary to certify MROs; and
 - (5) At least every five years, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify and/or train physicians as MROs for federal workplace drug testing programs must submit their qualifications and, if applicable, a sample examination. Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, the course syllabus and materials, documentation that the continuing education courses are accredited by a professional organization, and, if applicable, the delivery method and content of the examination. Each approved MRO training/certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the Internet at <http://www.samhsa.gov/workplace/drug-testing>.

Section 13.3 What training is required before a physician may serve as an MRO?

- (a) A physician must receive training that includes a thorough review of the following:
 - (1) The collection procedures used to collect federal agency specimens;
 - (2) How to interpret test results reported by HHS-certified laboratories (e.g., negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);
 - (3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;
 - (4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for

all authorized specimen types;

(5) Procedures for interpretation, review (e.g., donor interview for legitimate medical explanations), and reporting of results specified by any federal agency for which the individual may serve as an MRO; and

(6) Training in Substance Abuse including information about how to discuss substance misuse and abuse, and how individuals that test positive can access services.

(b) Nationally recognized entities or subspecialty boards that train or certify physicians as MROs should make the MROs aware of prevention and treatment opportunities for individuals after testing positive.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and (for urine) substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.17(d) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from

the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

- (2) Interview the donor when required;
- (3) Make a determination regarding the test result; and
- (4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of 2 years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen, as addressed in Section 8.6.

Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

(a) When the HHS-certified laboratory reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports multiple results for the primary (A) specimen, as the MRO, you must follow the verification procedures described in 13.5(c) through (f) and:

- (1) Report all verified positive and/or refusal to test results to the federal agency.
- (2) If an invalid result was reported in conjunction with a positive or adulterated result, do not report the verified invalid result to the federal agency at this time. The MRO reports the verified invalid result(s) for the primary (A) specimen only if the split specimen is tested and reported as a failure to reconfirm as described in Section 14.5(c).

(c) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor provides a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency for all drugs except codeine and/or morphine as follows:

(i) For codeine and/or morphine less than 150 ng/mL and no legitimate medical explanation: the MRO must determine if there is clinical evidence of illegal use (in addition to the drug test result) to report a positive result to the agency. If there is no clinical evidence of illegal use, the MRO reports a negative result to the agency.

(ii) For codeine and/or morphine at or above 150 ng/mL and no legitimate medical explanation: the MRO reports a positive result to the agency. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(d) When the HHS-certified laboratory reports an adulterated result for the primary (A) oral fluid specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the federal agency because the oral fluid specimen was adulterated.

(e) When the HHS-certified laboratory reports an invalid result for the primary (A) oral fluid specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result.

(1) If the donor provides a legitimate explanation (e.g., a prescription medication), the MRO reports a test cancelled result with the reason for the invalid result and informs the federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor.

(i) If the second specimen collected provides a valid result, the MRO follows the procedures in Section 13.5(a) through (d).

(ii) If the second specimen collected provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (e.g., urine).

(f) When the HHS-certified laboratory reports a rejected for testing result on the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor.

Section 13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?

(a) When another specimen type (e.g., urine) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, the MRO consults with the federal agency. The federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of oral fluid to complete the test;

(ii) The consequences of the appropriate federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid and is highly likely to prevent the employee from providing a sufficient amount of oral fluid for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternative specimen type (e.g., urine) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has or, with a high degree of probability, could have precluded the employee from providing a sufficient amount of oral fluid. As the MRO, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (i.e., authorized by the Mandatory Guidelines for

Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

Section 13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes him or her from providing a sufficient specimen for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the federal agency does not authorize collection of an alternative specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient oral fluid specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the

agency authorize collection of an alternate specimen type (e.g., urine) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6(b)(1)] exists, making provision of a sufficient oral fluid specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (e.g., the federal agency is not authorized to allow the donor to begin or resume performing official functions because a negative test is needed for that purpose).

Section 13.8 Who may request a test of a split (B) specimen?

(a) For a positive or adulterated result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that his or her specimen was reported positive, adulterated, or (for urine) substituted to request a test of the split (B) specimen. The MRO must inform the donor that he or she has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or (for urine) substituted result is being reported to the federal agency on the primary (A) specimen.

Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (e.g., teleprinter, facsimile, or computer).

Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and (for urine) substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

Section 13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory?

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with the HHS-certified laboratory that may be construed as a potential conflict of interest.

Subpart N - Split Specimen Tests

Section 14.1 When may a split (B) specimen be tested?

(a) The donor may verbally request through the MRO that the split (B) specimen be tested at a different (i.e., second) HHS-certified oral fluid laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or (for urine) substituted.

(b) A donor has 72 hours to initiate the verbal request after being informed of the result by the MRO. The MRO must document in his or her records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) oral fluid specimen cannot be tested by a second HHS-certified laboratory (e.g., insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency that the test must be cancelled and the reason for the cancellation. The MRO directs the federal agency to ensure the immediate recollection of another oral fluid specimen from the donor, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified oral fluid laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or (for urine) substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoff concentrations established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or

metabolite that was reported positive in the primary (A) specimen.

Section 14.3 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported adulterated?

(a) The HHS-certified laboratory must use its confirmatory specimen validity test at an established limit of quantification (LOQ) to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO.

Section 14.5 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split oral fluid specimen as:

(a) Reconfirmed the drug(s) or adulteration result. The MRO reports reconfirmed to the agency.

(b) Failed to reconfirm a single or all drug positive results and adulterated. If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm [specify drug(s)] and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm [specify drug(s)] and a refusal to test to the agency and

indicates the adulterant that is present in the specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) Failed to reconfirm a single or all drug positive results and not adulterated. The MRO reports to the agency a failed to reconfirm result [specify drug(s)], cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(d) Failed to reconfirm a single or all drug positive results and invalid result. The MRO reports to the agency a failed to reconfirm result [specify drug(s)] and gives the reason for the invalid result], cancels both tests, directs the agency to immediately collect another specimen and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and adulterated. The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office official responsible for coordination of the drug-free workplace program regarding the test results for the specimen

(f) Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated. The MRO reports a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO

shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and invalid result. The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the Drug-free Workplace Program regarding the test results for the specimen.

(h) Failed to reconfirm adulteration. The MRO reports to the agency a failed to reconfirm result (specify adulterant) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) Failed to reconfirm a single or all drug positive results and reconfirmed an adulterant. The MRO reports to the agency a reconfirmed result (specify adulterant) and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed result (adulterated) although Laboratory B failed to reconfirm the drug(s) result.

(j) Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterant. The MRO reports to the agency a failed to reconfirm result [specify drug(s) and adulterant] and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) Failed to reconfirm at least one drug and reconfirmed the adulterant. The MRO reports to the agency a reconfirmed result [specify drug(s) and adulterant] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on

the reconfirmed drug(s) and the reconfirmed adulterant although Laboratory B failed to reconfirm one or more drugs.

(l) Failed to reconfirm at least one drug and failed to reconfirm the adulterant. The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s) and adulterant]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterant.

Section 14.6 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (e.g., teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

Section 14.7 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

Subpart O - Criteria for Rejecting a Specimen for Testing

Section 15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

- (a) The specimen ID number on the specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;
- (b) The primary (A) specimen label/seal is broken or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;
- (c) The collector's printed name and signature are omitted on the Federal CCF;
- (d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen; or
- (e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as

the primary (A) specimen.

Section 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the HHS-certified laboratory may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot recover the collector's signature, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-federal form or an expired Federal CCF, the HHS-certified laboratory must test the specimen and also attempt to obtain a memorandum for record explaining why a non-federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?

(a) The following omissions and discrepancies on the Federal CCF that are received by

the HHS-certified laboratory are considered insignificant and should not cause an HHS-certified laboratory to reject an oral fluid specimen or cause an MRO to cancel a test:

- (1) An incorrect laboratory name and address appearing at the top of the form;
- (2) Incomplete/incorrect/unreadable employer name or address;
- (3) MRO name is missing;
- (4) Incomplete/incorrect MRO address;
- (5) A transposition of numbers in the donor's SSN;
- (6) A telephone number is missing/incorrect;
- (7) A fax number is missing/incorrect;
- (8) A "reason for test" box is not marked;
- (9) A "drug tests to be performed" box is not marked;
- (10) A "specimen collection" box is not marked;
- (11) The lot number of the collection device used for the collection is missing;
- (12) The collection site address is missing;
- (13) The collector's printed name is missing but the collector's signature is properly recorded;
- (14) The time of collection is not indicated;
- (15) The date of collection is not indicated;
- (16) Incorrect name of delivery service;
- (17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or
- (18) The donor's name inadvertently appears on the HHS-certified laboratory copy of the

Federal CCF or on the tamper-evident labels used to seal the specimens.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory are considered insignificant and should not cause an MRO to cancel a test:

(1) The testing laboratory fails to indicate the correct name and address in the results section when a different laboratory name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print his or her name;

(3) The certifying scientist or certifying technician fails to print his or her name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies are considered insignificant only when they occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector or HHS-certified laboratory (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 15.4 What discrepancies may require an MRO to cancel a test?

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or (for urine) substituted; or

(3) The electronic report provided by the HHS-certified oral fluid laboratory does not contain all the data elements required for the HHS standard laboratory electronic report for a specimen being reported drug positive, adulterated, invalid result, or (for urine) substituted.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that he or she inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory. If, after at least 5 business days, the laboratory does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P - Laboratory Suspension/Revocation Procedures

Section 16.1 When may the HHS certification of a laboratory be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension,

requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines.

Reviewing Official. Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 16.3 Are there any limitations on issues subject to review?

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the relevant Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

Section 16.4 Who represents the parties?

The appellant's request for review shall specify the name, address, and telephone number

of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone number of the respondent's representative.

Section 16.5 When must a request for informal review be submitted?

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 16.6 What is an abeyance agreement?

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period, advising whether the dispute has been resolved. If the dispute has been resolved, the request for

review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 16.7 What procedures are used to prepare the review file and written argument?

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) Appellant's Documents and Brief. Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) Respondent's Documents and Brief. Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug testing, which is tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential

documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) Reply Briefs. Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) Cooperative Efforts. Whenever feasible, the parties should attempt to develop a joint review file.

(e) Excessive Documentation. The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 16.8 When is there an opportunity for oral presentation?

(a) Electing Oral Presentation. If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) Presiding Official. The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) Preliminary Conference. The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying

issues, stipulations and admissions, limitations on evidence and witnesses that will be presented at the hearing, time allotted for each witness and the hearing altogether, scheduling the hearing, and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) Time and Place of the Oral Presentation. The presiding official will attempt to schedule the oral presentation within 30 days of the date the appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) Conduct of the Oral Presentation.

(1) General. The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) Burden of Proof/Standard of Proof. In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) Admission of Evidence. The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant,

immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) Motions. The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) Transcripts. The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) Obstruction of Justice or Making of False Statements. Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) Post-hearing Procedures. At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 16.9 Are there expedited procedures for review of immediate suspension?

(a) Applicability. When the Secretary notifies an HHS-certified laboratory in writing that its certification to perform drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the HHS-certified laboratory received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) Reviewing Official's Response. As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) Review File and Briefs. Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) Oral Presentation. If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7-10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct

the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) Written Decision. The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7-10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) Transmission of Written Communications. Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile, secured electronic transmissions, or overnight mail.

Section 16.10 Are any types of communications prohibited?

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 16.11 How are communications transmitted by the reviewing official?

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and federal holidays. However, if a due date falls on a Saturday, Sunday, or federal holiday, then the due date is the next federal

working day.

Section 16.12 What are the authority and responsibilities of the reviewing official?

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 16.13 What administrative records are maintained?

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 16.14 What are the requirements for a written decision?

(a) Issuance of Decision. The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may

remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) Date of Decision. The reviewing official will attempt to issue his or her decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) Public Notice. If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

Section 16.15 Is there a review of the final administrative action?

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

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